EXHIBIT 509

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION
MDL No. 1968

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION	VIDEOTAPED DEPOSITION OF: MARK G. KENNY VOLUME I

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TRANSCRIPT of the stenographic notes of the proceedings in the above-entitled matter, as taken by and before CAROL ANN SHEPARD, a Certified Court Reporter of the State of New Jersey, held at the MARRIOTT NEWARK AIRPORT HOTEL, 1 Hotel Road, Newark, New Jersey, on Tuesday, June 29, 2010, commencing at 8:30 in the forenoon.

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ALSO PRESENT:

Adam DiCola, Videographer

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E X H I B I T S

THE VIDEOGRAPHER: Good morning. We are on the record at 8:41 A.M., June 29, 2010. This is the videotaped deposition of Mr. Mark G. Kenny in the matter of In Re: Digitek Product Liability Litigation, in the United States District Court for the Southern District of New York, MLP Case No. 2:09-CV-121.

This deposition is being held at the Marriott at Newark Airport Hotel, located at 1 Hotel Road in Newark, New Jersey.

I am the videographer. My name is Adam DiCola of Rennillo Reporting. Our court reporter is Carol Ann Shepard, also with Rennillo Court Reporting.

Will counsel please state their appearances for the record.

MS. CARTER: Meghan Carter, Motley Rice, for the Plaintiffs.

MR. MILLER: Peter Miller from The Miller Firm for Plaintiffs.

MR. MORIARTY: Matt Moriarty from Tucker Ellis for the Actavis Defendants.

MR. ANDERTON: Michael Anderton from Tucker, Ellis & West, also for the Actavis Defendants.

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MR. KAPLAN: Harvey Kaplan, Shook, Hardy & Bacon for Mylan.
MR. MORIARTY: Just so the record is clear, this is the Southern District of West Virginia that this litigation is in, not New York.
Ready?
M A R K G. K E N N Y, 2 SpyGlass Court, Annandale, New Jersey, having been duly sworn, testifies as follows:
EXAMINATION BY MR. MORIARTY:
Q. Tell us your full name, please.
A. My name is Mark George Kenny.
Q. All right. And, Mr. Kenny, have you ever had your deposition taken before?
A. Never.
Q. First time. Okay.
I'm sure that either Mr. Miller or Ms. Carter has told you that I'm going to ask you a lot of questions today.
Okay?
They've done that, I assume?
A. Correct.
Q. And you know we probably will be here all day. Is that right? And even then we may not finish.

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Do you know that?
A. Correct.
Q. If you don't know the answer to my question, please tell me that you don't know.
All right?
A. Yes, sir.
Q. If you don't understand my question, please tell me that you don't understand me.
Okay?
A. Sure.
Q. If you need to look at a document, including your report, your resume or anything else, in order to answer my question, please do that.
Okay?
A. Yes, sir.
Q. I don't want you to guess.
You're going to have to keep your voice up loud because the court reporter has to hear you.
All right?
A. Okay.
Q. And if you say uh-huh or uh-uh, I will say is that a yes or is that a no --
A. Right.
Q. -- because she needs to understand these things in plain English.

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Okay?
A. Surely.
Q. Now, at some point, we will mark your resume as Exhibit 47. But that was made Appendix A to your report in this case.
Is --
A. Correct.
Q. -- that right?
And I notice that you live on SpyGlass Court.
Is that right?
A. That is correct.
Q. And the name of your consulting company is the SpyGlass Group.
Is that right?
A. That is correct.
Q. How many employees does SpyGlass Group have?
A. We have no employees.
Q. You are not even employed by SpyGlass?
A. Well, I'm an employee under a sub -- Subchapter S, yes, and so is my wife.
Q. And you are the only employees?
A. That is it.
Q. Do you have any agreements with other

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people who are independent contractors and do consulting work for you?
A. We have agreements when there is a project.
Q. All right. So on the -- on the Digitek project, how many people reviewed documents and worked to help you prepare this report?
A. There were two additional people, one Dr. Sal Romano, and my wife, who proofed it.
MR. KAPLAN: Dr. who?
THE WITNESS: My wife.
MR. KAPLAN: No, no. Dr. --
THE WITNESS: Dr. Sal Romano.
Q. What's your wife's name?
A. Denise.
Q. Denise Kenny?
A. That's correct.
Q. Did she do any technical input?
A. None whatsoever.
Q. And who is Sal Romano?
A. Sal Romano is also a consultant. He is a core member of our consulting group and a former quality assurance professional -- when I say former, I mean working full time for a large company, Johnson & Johnson -- who has done consulting for

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over 10 years.
Q. All right. So I assume that when SpyGlass -- when you or SpyGlass Group are asked to do, say, a consulting project for a pharmaceutical company --
A. Correct.
Q. -- if you can't staff that by yourself, you reach out to people with whom you have previous relationships and bring them in as consultants on that project.
Is that right?
A. That's correct.
Q. Okay. How old are you?
A. I'm 61 years old.
Q. Appendix B to your report, which we will also have as an exhibit, is -- is referred to as "References."
Is that correct?
A. That is correct.
Q. And on here are 60 listings.
Is that right?
A. That is correct.
Q. Have you reviewed anything else besides these 60 listings since you drafted the report?
A. Since I drafted the report, yes.

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Q. All right. Can you tell me what else you reviewed since drafting this?
A. I looked at some Mylan depositions. There was nothing I felt substantive.
Q. Whose depositions?
A. I don't recall the name.
Q. Well, there was a -- Chuck Koon was deposed.
Did you look at his deposition?
A. I briefly went through it.
Q. Did you look at Lianna Radtke's deposition?
A. No, I did not.
Q. I think there was a -- Susie Wolf was deposed.
Did you look at her deposition?
A. I did not.
Q. Anything else that you can recall reviewing since you drafted your report?
A. No.
Q. Did you leave J&J in 2004?
A. Yes, I did.
Q. Why?
A. I was offered, as was everybody in the United States, an early retirement package. I had

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the option of leaving or I had the option of staying.
Q. And you took the option of the early retirement package?
A. Yes. Indeed. That's correct.
Q. All right. Did you meet with and talk with Mr. Miller either last night or this morning --
A. No.
Q. -- to talk about any last-minute developments before your deposition?
A. Nothing.
Q. Have you heard anything from anyone amongst the plaintiffs' lawyers about what happened during Mr. Farley's deposition yesterday?
A. No. Nothing.
Q. So what -- give me a general idea of what consulting projects you work on now under this banner of the SpyGlass Group.
A. Okay. I would say half of the projects that I work on are auditing, auditing of medical device, drug companies. And that would be for GMP purposes, also for ISO Regulation 1345:2003.
The other projects are really assistance in risk determinations, establishment of quality systems, establishment of quality plans,

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establishment of master validation plans, reasonably high-level documents that would be submitted to the management board or management level of a company.
Q. Do you ever help companies remediate 483s or warning letters?
A. As a consultant?
Q. Yes.
A. No.
Q. How much of your consulting work is spent on solid oral dose?
A. You mean over the six-year period?
Q. Yes.
A. I would say within the last two years, 30 percent.
Q. And how much of it is device work?
A. It would be over half. 60 percent.
Q. In the six years of SpyGlass Group consulting, have you done any 483 or warning letter remediation work?
A. I would have to answer that yes.
Q. When you worked for J&J in your various capacities over the years, were part of your duties to look at 483s and warning letters --
A. Of course.
Q. -- and help the company remediate them?

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A. Yes.
Q. In the process of doing that, as an example, if you got a 483 that had to do with a manufacturing issue, would it be part of your job to look at batch records?
A. It could be, but probably would not be.
Q. Why?
A. Because I would not get involved at that level. I would get involved more at a strategic level, determining whether the action plans are comprehensive, rather than going through the detail of reading batch records that normally would be done by somebody else.
Q. But as part of the project --
A. Yeah. You're talking -- are you referring to a 483 project, or are you referring to in general a project?
Q. A 483 or warning letter remediation.
A. No. I -- I take that back. Yes, I would.
Q. You would personally look at them or --
A. Yes.
Q. -- you would supervise somebody?
A. No. I would do it myself.
Q. All right.

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A. But would not -- I would not -- that is not a major portion of what I do.
Q. But --
A. For -- for 483 remediations.
Q. Sure.
A. I do a high -- an extraordinary number of batch reviews, capital reviews and the like as part of my consulting practice over the last six years.
Q. So, for example, if somebody is looking for a way to improve a manufacturing process, for example, looking at batch records regarding that process is something you would do?
A. That's correct.
Q. And if there was some question about whether a process was validated or robust or staying in validated control, looking at the batch records over time would be one of the things that would be important to do?
A. That's correct.
And they would rely on me to be able to make that determination.
Q. All right. In your years at J&J or as a consultant, have you ever been involved in the manufacture, QA or QC of a Digoxin product?

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A. Never.
Q. Now, over the years, in your work, have you come to appreciate the difference between possibility and probability?
A. I would think I do.
Q. All right. So probability, for example, is generally defined as more likely than not.
Would you agree with that?
A. I would say that's reasonably fair.
Q. And possibility is more in the realm of speculation.
Is --
A. Correct.
Q. -- that true?
So that can -- can happen, might happen, that's possibility and speculation; right?
A. I would have to think about the terms, but that -- that, perhaps, is a way of explaining it. I would not use those terms precisely.
I would determine risk levels.
Q. Now, your report in this case, we're going to ultimately mark as Exhibit 48, but I would like you to take a look at page 23 of that.
A. Yes, sir.

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Q. Do you have that in front of you?
A. Yes, I do.
Q. And on this page, there is a section called "Quality and Quality Systems SpyGlass Group Summary."
Do you see that?
A. Yes, I do.
Q. And essentially, after the first 22 pages of your analysis, this is the one-sentence essence of your opinion.
Is that right?
A. I suppose you could put it that way.
Q. Okay. And it says that: "It is my opinion, to a reasonable degree of certainty, that Actavis failed to establish reliable and GMP compliance systems and procedures, resulting in the release of adulterated product from at least the period of 2004 to 2008."
A. Correct.
Q. Right? Okay.
And among the things that you relied on in this Appendix B are a number of FDA documents, like 483s and warning letters; correct?
A. That is correct.
Q. And what are known as EIRs or

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establishment inspection reports?
A. That is correct.
Q. I don't see anywhere on Exhibit B references to batch numbers, other than Batch 70924 A.
Did you review any other batch records?
A. Yes, I did. Perhaps two more.
Q. Which ones?
A. I don't recall the batch numbers.
Q. All right. Do you -- do you know how many recalled batches there were in the Digitek recall of April of 2008?
A. No, I don't.
Q. There were 151 or 152 of them.
Is what you're telling me now that you may have reviewed as many as just three of those?
A. Batch records, yes. That's all I -- I had available to me.
Q. Do you know when batches were manufactured, when batches were first manufactured that were part of the recall?
A. I would assume, and I think it's a safe bet, that the batches would have been manufactured within the expiration date that it was in the field.
In other words, all batches would have

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been recalled that were still within the expiry date.
Q. Do you know how long Digitek's expiration date is?
A. For what product?
Q. Digitek.
A. Oh, for Digitek? No, I don't.
Q. Did you review any method operating instructions --
A. Yes.
Q. -- from Actavis?
A. Yes, I did.
Q. How many of them?
A. Probably a dozen plus.
Q. Are they listed in Exhibit B?
A. No.
Q. Appendix B?
A. No. I had no reference to them.
Q. What do you mean you had no reference to them?
A. In other words, I had no observation to those particular documents.
Q. What does that mean?
A. Could you restate your question?
Q. What do you mean "observation"?

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Are you talking about in the regulatory sense of observation being --
A. Could you repeat the first question, please?
Q. I'm going to ask you a new question.
MR. MILLER: Well, I think he wants to make sure he understands the line of questioning.
You asked him the first question. If you reask the first question, then perhaps he can phrase it.
Right -- right now, he's confused about what the line of questioning is.
Q. Well, there are no MOIs listed in Appendix B. You said it's because you had no observations about it.
A. I read certain documents. And I had no comment on those.
Q. Okay. So, for example, if MOI 145 has to do with QC testing of Digitek, you didn't find anything deficient, for lack of a better term, in MOI 145.
MR. MILLER: Object. I'll object. If you'd let -- allow me, I'll object; and when I'm done, then you can finish.
I'm sorry. Excuse me. But objection.

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Misstates previous testimony.
It's okay to answer.
A. Okay. If your question -- if you're asking me did I look at documents and see deficiencies in the documents, the answer to that would be yes, I did see deficiencies in documents that do not appear in here.
Q. That's not what I'm asking you.
Did you review MOI 145?
A. I don't recall.
Q. Well, if you found a deficiency in a method operating instruction regarding a key manufacturing or testing process for Digitek, is it likely that you would have put it in your report?
A. If I -- if it -- it was significant and if I saw it, I may have put it in the report, if I felt it was important.
Q. Did you understand -- well, first of all, have you ever done litigation consulting before this case?
A. No, I have not.
Q. Did either Mr. Miller or anybody from Motley Rice let you know that the purpose of this report was to put us on notice of what your opinions were?

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A. Yes.
Q. And what documents you relied on to reach those opinions?
A. Right. And I provided those documents in the box.
Q. I understand that.
And you also listed 60 items that you reviewed.
A. Correct.
Q. So let me get back and make sure I understand this.
MOI 145 has to do with QC testing for Digitek. I want you to assume that.
A. Okay.
Q. If you found that the QC testing process for Digitek was deficient in some way, technically or by some GMP standard, and you reviewed the document, is it likely you would have commented on it in your expert's report?
A. Okay. I think it's important to understand that I am not an analytical chemist.
My experience is -- education experience is as an engineer, both mechanical engineer and a biomedical engineer in graduate school.

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When I review laboratory records, I look at them from a compliance standpoint, not a technical standpoint.
So I would review them, making sure that there would be certain content in there in terms of whether they appeared complete.
I would also be looking at -- if it was a test method, which I think you are referring to, I would ask whether there was a method validation study in order to ascertain whether the test method is valid.
That is the question that I would ask. And that would, to me, be among the most important questions.
Q. Okay. So if the technical aspects of MOI 145 for the lab testing of Digitek, would you feel more comfortable deferring to a quality control chemist for opinions on whether that MOI was consistent with the United States Pharmacopeia?
A. I would ask the research person that, not the quality control person.
The research person is the person who understands the regulations, is responsible for developing the procedure.
The quality control person is not

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responsible for the technical content of that document. The quality control person is responsible for executing that document, is responsible for being part of the method transfer, is not even part of the method validation study.
That person is an expert in performing reproducible studies and getting accurate results.
Q. But certainly the quality control chemist is the person who actually has to be performing the study --
A. That's correct.
Q. -- to get the results that are documented in batch records; right?
A. That's correct. The basis of the numbers that are in specification. They would not necessarily understand why those numbers were selected.
Q. Okay. These 483s that we have been talking about are regulatory documents sent to a company by the FDA; correct?
A. That is correct.
Q. And a warning letter is also a regulatory document sent to a company by the FDA?
A. That's correct.
Q. I'm handing you what's been marked as

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Exhibit 63.
(Exhibit 63, Chapter 4, Advisory Actions, was marked for identification.)
Q. This is Exhibit 64.
(Exhibit 64, Chapter 10, Other Procedures, was marked for identification.)
Q. Have you ever seen these documents before?
A. I have not.
Q. These are from the Regulatory Procedures Manual of the FDA.
Have you ever seen any parts of the Regulatory Procedures Manual for the FDA?
A. I have not.
Q. First, I'd like you to take a look at Exhibit 63.
A. Okay.
Q. First page, it's entitled "Warning Letters"; is it not?
A. Yes, it is.
Q. And one, two, three, four lines down it says: "Warning letters are issued to achieve voluntary compliance and to establish prior notice."
Do you agree with that?
A. Yes.

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Q. Go to the next page, please, which is 4-2, the fourth full paragraph.
It says: "A warning letter is informal and advisory."
Do you agree with that?
A. Do I agree with that from a practical standpoint?
Q. Well, do you -- sure.
A. All right. Let's put it this way --
Q. Do you agree or disagree with the FDA's own Regulatory Procedures Manual?
A. May I ask you a question?
Q. Actually, you can't. I ask questions.
A. All right. I will state what I think.
From a --
MR. KAPLAN: Just answer the question, because I'm going to move to strike any answer that's not responsive.
Please answer just the question that's asked. No statements, no speeches.
MR. MILLER: Well, I think his statement is in response to the question.
MR. MORIARTY: Well, let him make his statement, and I'll deal with it. I haven't heard his statement.

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MR. MILLER: That's what we're trying to do, Matt. Let's do it.
Go ahead, make your statement.
A. Could you ask the question?
Q. Yes. At page 4-2 of the FDA's Regulatory Procedures Manual, it says: "A warning letter is informal and advisory."
Do you agree with that statement?
MR. MILLER: And I'm going to object to reading one sentence out of a document he's never seen before and asking him if he agrees with it.
I think he ought to take the time to read at least the whole paragraph and put it in context.
Q. It's a three-sentence paragraph. Go ahead and read it.
A. From an FDA standpoint, I agree with this.
Q. The next sentence says: "It communicates the agency's position on a matter, but does not commit FDA to taking enforcement action."
Do you agree with that?
A. Yes, I do.
Q. The next sentence says: "For these reasons, FDA does not consider warning letters to be

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final agency action on which it can be sued."
Do you agree with that?
A. I don't have the basis to disagree. I don't know what the basis for suit -- for forming a suit would be.
Q. Do you know what "final agency action" is?
A. No. I don't know the term.
Q. Now, are warning letters considered the second step in this sort of note -- written notification chain?
A. From a business standpoint, yes.
Q. The first step would be the 483.
Is that right?
A. Correct.
Q. And a 483 is also informal and advisory.
Is it not?
A. I don't perceive it as that.
Q. Well --
A. I perceive -- I perceive it as a company put on warning that you have some potentially very significant issues, or it would not have been in the 483, and that you're expected to understand those issues, investigate those issues,

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determine whether they represent systemic issues, and then put in corrective action plans that are appropriate with the risk determination that you've made as a result of your investigations.
Q. Do you have any opinion about whether the FDA considers 483s to be final agency action?
A. I don't have the experience to answer that question.
Q. All right. Have you ever worked for the FDA?
A. I have not worked for the FDA.
I worked with the FDA.
Q. Well, I assume what you mean by that is when you were at J&J, sometimes you had to interact with FDA regarding recalls or investigations or something else; correct?
A. I would not put it that way. So if you want me to put it my way --
Q. How did you interact with FDA?
A. I interacted with the FDA during an inspection by the FDA if I determined in the company, within the company I work for, that I would be additive to the process.
I worked with the FDA on, for example, a home HIV test, which was basically the first --

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first concept of an HIV test that the consumer would participate in the testing itself.

The regulations really didn't exist that were specific to that, so the FDA had to -- had to try to understand the technology, had to try to interpret the GMP regulations.

And we assisted the FDA in doing that. And they assisted us in helping establish development validation. Because, again, this -- this was a novel product.

So I have worked directly with the FDA on items like that.

Q. Essentially, your whole working career from 1974 to 2004 was with different J&J companies. Is that right?

A. That's correct.

Q. All right. In your years at J&J, was any part of J&J under a consent decree?

A. To my knowledge, no.

Q. To the best of your knowledge, while you were at J&J over those years, were any products ever seized by the FDA?

A. Not to my knowledge.

Q. Were any of the companies that you worked for at J&J ever given Form 483s by the FDA?

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A. Yes.

Q. Were any companies that you worked for at J&J given warning letters by the FDA?

A. Yes.

Q. When you were with J&J, did J&J have product recalls?

A. Did J&J? You mean the $60 billion company, of course?

Q. Did any of the business units for which you worked have recalls?

A. I only had one recall in my entire career, which had nothing to do with compliance.

Q. What did it have to do with?

A. It had to do with two items. I'm sorry. Had to do with one item. And it's reasonably complex. Would you like me to go through the description of what happened?

Q. No. I'd like the Reader's Digest, simple version.

A. I will do my very best.

We sold a product, a home HIV test, which had a mailer. The customer participated in the test by pricking their finger and putting three blood droppings on a sample card. It was a paper card, the same as -- anyway, it was a paper card

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designed for that purpose, used by the FDA for the last 50 years.

They would then send -- mail that to the -- to the test center, which was under contract with us. And they would actually do the testing of that and determine whether or not it was positive or negative, the results.

Okay? Now, the mailer that Johnson & Johnson initially used was not a -- a -- a Fed Ex-type mailer. It was a normal mailer that took three days to arrive at the lab.

The competition, six months after we launched the product, put in next-day mailing service.

Unbeknownst to everybody in the company that I was aware of but sales, they decided to develop mailers to expedite this.

So they went into the field, pulled out the mailer for the three-day, you know, cycle and put in the mailer for the one-day cycle.

Okay. I was -- I was not aware of it. I would not have authorized it, but it happened. It sounds innocent.

The product was kept behind the counter in most instances. It was almost a $40 product.

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They were afraid -- pharmacists were afraid that the product would be stolen.

The salesmen, I was told, were given instructions to physically place the mailer on the product.

So when they went into the pharmacy, sometimes they did it, apparently. Sometimes they did not. The pharmacy frequently would say -- not frequently; we didn't have that many examples -- but would say, I will do it for you because it is behind the counter. Don't worry about it. Leave the mailers. How many products do I have? Three. Leave three mailers.

The pharmacists made an error, in that when the competition came out, it was kind of like Walmart. They made a product that looked identical in color, identical in shape, so that when the pharmacist went to put the mailer onto the -- onto Confide, which was the product, they -- and I don't know if it was six instances, eight instances -- put them on the competitive product.

Q. Okay. Let me stop --

A. Can I finish the concept?

Q. No. Let me just stop you for a second. I think I see where this story is going.

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I take it that this recall was not because of the quality or integrity of the HIV testing itself?
A. That's correct. As a matter of fact, we were above, if you will, the gold standard.
Q. Okay. The recall was for regulatory reasons related to FDA being involved in labeling and other things post --
A. No. No. That's not correct.
Q. -- unrelated to the test itself?
A. No. It's related to the test. The samples went to the wrong lab. They went to the competition.
Q. No. That's not what I'm asking.
The quality or integrity of the HIV test itself was not the reason for the recall?
A. The integrity -- in other words, if the samples arrived to the correct lab, and those samples were -- see, we would receive competitive samples.
Could the integrity of that test be compromised? It is conceivable, because we don't know how their paper was made. We don't know their test methodology. We only know what we did. They had the wrong competitive information.

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So is it conceivable? Yes. Is it -- you're talking about probabilities. Probability would be low.
Q. Okay.
A. But there is a probability that it would not be tested. So you would have somebody who had -- who had -- would not have gotten the results.
Q. Okay. Among the things that you reviewed, in Appendix B, Item Number 7 is a website?
A. Item Number 7 is a website. Correct.
Q. Now, is that a part of the FDA's website?
A. No. No, it is not.
Q. So this is some --
A. Another consulting firm's.
Q. Learning Plus, Inc.?
A. I don't recall the exact -- I'd have to pull the website up.
Q. But this is their description of what the warning letter is and later what GMPs are; correct?
A. No. No.
Q. Well, I --
A. That is --
Q. -- printed --

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A. That is specific to the reference.
Q. I printed your Reference B. Okay? There is the definition of a warning letter.
A. Right.
Q. There is -- from Learning Plus, Inc.
Do you see that?
A. Yes.
Q. There's about this site.
Do you see that?
A. Yes.
Q. There's their definition of GMPs.
Do you see that?
A. Yes.
Q. Okay. This is not an FDA website?
A. That is correct.
Q. What I would call the official definition of what a warning letter is, according to the FDA; correct?
A. That is correct.
Q. Do you have any opinion on whether or not an establishment inspection report constitutes final agency action of the FDA?
A. Yes. It does not constitute final action.
Q. All right. Tab 9 in your Appendix B is

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Plaintiffs' Exhibit 147. It is an E-mail about a 483.
Do you have that?
A. Do I have it in my -- yes, I do. Would you like me to try to pull it?
Q. Or you can just use mine.
A. If it's correct.
Q. What do you mean if it's correct? You think I'm BSing you?
MR. MILLER: Objection. That's not what he was saying.
MR. MORIARTY: I don't know what he was saying.
Q. First of all, the first page of Exhibit 147 is an E-mail; correct?
A. That is correct.
Q. The next page is a 483 from the FDA to Actavis Totowa from the inspection of March 18 through May 20, 2008.
Do you see that?
A. Yes. This is -- 147 continued into the 483?
Q. It's one exhibit.
A. Is this a new exhibit?
Q. It's one exhibit.

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A. Okay.
Q. It is a plaintiffs' exhibit.
A. Okay.
Q. Do you see this Observation 2?
A. Yes, I do.
Q. Underneath Observation 2, there is a statement that says: "Drug products failing to meet established specifications and quality control criteria are not rejected."
Do you see that?
A. Yes, I do.
Q. In Chuck Koon's deposition, he said that this is essentially the Turbo software restatement of the language from an FDA regulation.
Do you agree with that?
A. Oh, I don't know.
Q. Okay. And then what Chuck Koon said is that under specifically is the example that an FDA inspector gives based on their inspection.
Do you know anything about that?
A. No. I -- in other words, if you're stating that this is the highlight, and this substantiates that highlight, this is -- this is the, you know, front page heading, and then they go into specifics to support their broad statement.

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Q. That's not what I asked you.
MR. MILLER: Objection. That is what you asked.
A. Would you ask it again, please.
MR. MORIARTY: You will not find that statement from me on this record, Pete. Don't do that.
MR. MILLER: I will do that.
MR. MORIARTY: And don't coach him.
MR. MILLER: And don't point at me and tell me not -- what not to do.
MR. MORIARTY: Don't coach him.
MR. MILLER: I'm not coaching anything. I'm pointing out what your -- the flaw of your statement was.
You asked about the top of the observation and the bottom.
MR. MORIARTY: Pete -- Pete, this is federal court. Objection and your basis. Don't start this. Okay?
MR. MILLER: No, Matt. I'm -- you started this. I'm just trying to point out your flaws, Matt.
Q. I asked you a very specific question. A witness named Chuck Koon, a quality assurance

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expert at Mylan, said that the FDA's Turbo software --
A. I'm not -- first of all, I'm not familiar with the FDA's --
Q. Okay.
A. -- Turbo software.
Q. I'm just asking you if you agree with Mr. Koon.
He said that this statement about drug products failing to meet established specifications is essentially the FDA's kicking out the regulation language.
And I asked you if you agreed with that. And you said you didn't know.
A. I don't know.
Q. Okay. FDA is charged with protecting public health, is it not?
A. Yes. It certainly is.
Q. Sometimes, when the FDA acts, it has to be flexible and act quickly to carry out its duty to the public.
Do you agree with that?
A. Yes.
Q. In your experience, does FDA sometimes act too hastily in ordering recalls of products?

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A. In ordering recalls, my experience is they do not act too hastily.
Q. In your experience, do they ever overreach?
A. Could you explain what you mean by "overreach"?
Q. Plain English definition of it.
A. Overreach what?
Q. Okay. Well, for example, in -- in the situation that you had with your HIV home health testing, was there some other fix for the problem, other than a recall, available?
A. Other than a recall? Yeah. We could have -- I suppose we -- no. There was no logical fix.
We could have gone out and inspected competitive product. First of all, we have no right to look at competitive product.
But conceivably, we could have gone and had our entire sales force go out, look for all the product they could find, which may or may not be all the product, and then pull the mailers off.
But the issue is compounded because people have the product. They may have the wrong mailer. They may keep the product for months. So

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the -- the only responsible behavior is to recall.
Q. All right.
A. And may I say that, as part of the companies that I've worked for, we would take a very, very conservative approach to recalls, probably far more conservative than the FDA would.
Q. All right. When you were at J&J, what percent of your personal work involved solid oral dose?
A. It depends upon the point in my career. There was a three-year career --
Q. Overall.
A. Overall? 8, 11, doing it recently. I'd say 12 years.
Q. Okay. And overall, J&J has had recalls of solid oral dose tablets or capsules even while you worked there; correct?
A. The $60 billion Johnson & Johnson company most certainly has had recalls.
Q. Okay. So I think there was Tylenol recall back in the '80s?
A. '83. I was somewhat involved in that.
Q. Okay. And did -- did J&J ever internally assess, to your knowledge, what percentage of the Tylenol that was recalled was

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actually somehow outside its specifications?
A. But that wasn't the issue. The issue was whether or not it was tampered by a -- an individual.
Q. Okay. What percentage of it was tampered with?
A. I don't know. I don't recall.
Q. Far less than --
A. Less than 100.
Q. 100 instances?
A. No. Far less than probably -- no. Far less -- no. The number of instances where -- if I was going to guess, I would guess less -- less than 10. In other words, they only had a few instances where the product was tampered with by whoever the felon was.
Q. Sure. Did -- in your career there at J&J, did they have recalls of other solid dose products, solid oral dose products?
A. I'm sure they did. I can't recite who they were. They weren't involved with companies that I had responsibility for.
Q. All right. But in those instances, either J&J could have voluntarily done a recall or

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FDA could have requested a recall, even if just a small percentage of the solid oral dose that had made it to market was possibly outside its specifications; right?
A. That is correct. That is possible.
Q. So when we talk about, I use the term "hasty" or "overreaching," you would agree that sometimes recalls are conducted even though the possibility of an actual defect and harm to the public is small; correct?
A. I would answer that question not in that way. I would answer the question as we don't know, and we would take a conservative approach and pull it back. And as part of the investigation subsequently, we'd get some knowledge of the breadth of the issue.
Q. All right. It's sort of an abundance of caution thing. Is that how you are referring to being conservative?
A. That's -- that's one way.
Q. All right. Your Reference B, Number 2, is 21 Code of Federal Regulations Part 210 and 211 regarding GMPs; correct?

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A. That is correct.
Q. And I'd like -- do you have a printout version of it?
A. No, I don't. Actually -- no, I don't.
Q. All right. This is your Tab -- your Reference 2.
MR. MORIARTY: Pete, you can come over here if you need to see it.
Q. Do you see that this is Part 210 of the GMPs?
A. Correct.
Q. And the next page, in 210.1, Section B --
A. Yes, sir.
Q. -- it says: "The failure to comply with any regulations set forth in this part, and in parts 211 through 226 of this chapter, in the manufacturing, processing, packing or holding of a drug shall render such drug to be adulterated under Section 50182B"; correct?
A. Yes.
Q. And then the last part of this long sentence says: "Shall be subjected to regulatory action"; correct?
A. That's exactly what it says.

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Q. All right. And what this section of the CFR is about is the regulatory powers of the FDA.
Is that right?
A. That's correct.
MR. MILLER: Object to the form. The document speaks for itself.
Q. To your knowledge.
A. Yes.
Q. Okay. You -- I didn't see anything about medical school, internships or residencies on your resume.
You're not a physician; right?
A. That is correct.
Q. So I assume that you are not going to be testifying about whether specific plaintiffs' injuries had anything to do with defective Digitek; correct?
A. That is correct.
Q. As far as I can understand your report and, obviously, the summary at page 23, your role is to talk about whether Actavis complied with certain good manufacturing practices.
Is that right?
A. That is correct.

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Q. And for this definition of adulteration, you are relying on CFR 351(b), I assume?
A. If that's what it says, yes.
Q. And this is Tab 5 of your Reference B.
Is that right?
A. I assume it's correct.
(Exhibit 39, FDA Printout, was marked for identification.)
Q. Now, that's Exhibit 39. This is a printout from the FDA's website.
Have you ever seen this before?
A. Let me just take a look at it.
I believe I have.
Q. And this particular section is called "Facts About Current Good Manufacturing Practices"; correct?
A. That's correct. This is -- this is somebody's interpretation of what the facts are. It's not a guidance document. It is a page in a -- in a website.
Q. But it is a page from the FDA's website?
A. Absolutely.
Q. All right. Now, go down to the second

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title that says "Why Are cGMPs So Important?"
MR. MORIARTY: When you type cGMP, the C is small and the GMP is large.
Q. The second sentence says: "In most instances, testing is done on a small sample of a batch (for example, a drug manufacturer may test 100 tablets from a batch that contains 2 million tablets) so that most of the batch can be used for patients rather than destroyed by testing."
Do you agree with that?
MR. MILLER: Again, I would object. I would ask you to give him an opportunity to read the whole paragraph before you ask him about a particular sentence inside a paragraph so he can put it in context.
Q. Okay. Do you need to read more or are you ready to answer questions?
A. I would like to read it.
Q. You can read the whole thing. Let me know when you're ready.
A. I've read it.
Q. Let's go down to -- and let me linger there a second.
From your experience, that is true in practice; correct?

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I mean, a manufacturer can't test them all, or there'd be nothing left to sell; correct?
A. That's correct. Of course.
Q. So I assume at J&J, the products that you were involved with had sampling plans?
A. Most certainly.
Q. All right. And at some point in the validation process or through inspections, FDA was aware of what those sampling plans were?
A. Well, if they reviewed them, yes.
Q. Okay. Let's go down to the fourth heading, "If a Manufacturer is Not Following cGMPs, Are Drug Products Safe for Use?"
Go ahead and read that whole section, because I'm going to ask you about it.
A. Okay.
Okay. I've read it.
Q. The first two sentences of that section essentially state what's in these regulations in Tabs 2 and 5 from your Reference B; right?
A. Okay.
Q. That if a drug is not manufactured in compliance with cGMP, the FDA considers it adulterated; correct?
A. That's correct.

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Q. The next sentence says: "It does not mean that there is necessarily something wrong with the drug."

Do you agree with that?

A. I think it's poor wording.

Q. How do you think it's poor wording?

A. Because the quality of a drug is dependent upon executing a series of steps, starting in the development process, going through -- going through development process, going through to technical transfer, going through to process validation, going through to routine -- writing procedures, etcetera, that are in place to control the quality, and then ultimately, just making sure that it's okay by taking a sample.

Because, of course, you don't know -- you don't know what you don't know, but what you do know is that at least you've looked at X number of samples, and those samples were good.

Since you've based your sampling upon your validated state, and you know you have content uniformity, you know that all the tablets are coming off the -- the production line within specification, therefore justifies, as the last step, taking a sample.

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So the -- I think this is poor wording.

Q. Okay. Well, let's -- let's get to the bottom of what it's saying.

The FDA could call a particular batch of tablets adulterated, could it not?

A. Yes.

Q. If it found a cGMP violation; correct?

A. Yes.

Q. All right. Let's stick with one batch for the time being.

A. Certainly.

Q. But if FDA -- if the manufacturer had done United States Pharmacopeia testing on tablets, and then the FDA itself did USP testing on tablets from that same batch and confirmed that they were within the USP's specifications, there would have been nothing wrong with those tablets; correct?

A. There would be nothing wrong with the tablets that they tested.

Q. Okay. And when there is --

A. If --

Q. When --

A. If -- may I say an if?

If there was a valid test method done by a qualified individual.

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So if we assume that the FDA and all these other tests that were done were qualified, that they had a validated test method, then we can assume, and it's fair to assume that the units that they tested, those tablets, those bottles, whatever they tested to get individual samples are within the specification.

Q. Okay.

A. If it's determined that it is.

Q. And the FDA allows you to draw certain conclusions from that because it's an appropriate sampling size; correct?

A. Tell me what you -- are you saying is the conclusion.

Q. All right. Well, let me -- let me ask you: If FDA -- do you know what a 484 is?

A. No. I am not familiar with that.

Q. You don't know what a 484 is?

A. I said --

MR. MILLER: Objection. Asked and answered.

Q. FDA comes to Johnson & Johnson and decides to take a sample from you of your product for independent testing.

A. Right.

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Q. Do you know what that process is?

A. Do -- I heard of it. I haven't been involved in it.

Q. All right.

A. Regulatory affairs department would interact with the FDA, not the quality assurance department.

Q. Well --

A. In -- in a situation like that.

Q. Well, if FDA independently tested a J&J product that you were involved in, what conclusions would -- and it passed all the specifications, what conclusions would you, at Johnson & Johnson, draw from that?

A. I would draw a conclusion that they took X number of samples, and the samples that they took were within specifications.

Since I know that my process is well developed, well characterized, since I know I have a validated process, since I know I have validated test methods, since I know I have qualified individuals conducting all of these studies, then I can make a conclusion that their test results confirmed that which I knew to begin with.

Q. So it's good news; right?

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MR. MILLER: Object to form.
Q. Okay. I'll use something more scientific.
It corroborates your processes and testing, doesn't it?
A. Yes. It certainly does.
Q. I didn't see on your Reference B that you looked at any of the process validation for Digitek.
Did you look at the process --
A. Yes.
Q. -- validation documents for Digitek?
A. I looked at two process validations. They were rather old. 1993, I believe, for .5 milligram Digitek. And there was -- there may have been another one. I don't recall.
Q. Well, and that was submitted to the FDA for purposes of the ANDA; correct?
A. Perhaps. I would assume that it was. I don't know. It doesn't say this was submitted. I don't have the submission.
Q. Did you ever see anywhere in the material that you reviewed a specific reference by FDA that Digitek testing methods, like MOI 145, were not validated?

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A. I believe there was one or two test methods not properly validated.
Q. Okay. Find it. I want to -- I want to hear from you where in all the material you reviewed there is a single reference by the FDA to a --
A. Test method.
Q. -- to a test method for finished tablets not being validated.
A. Well, you just added "finished tablets."
I would -- I would assume that, based upon your questioning and your challenge, that I would not find that.
So -- so I may have misspoken in terms of recalling a test method validation non-conformance.
Q. Let's go to the second paragraph in Exhibit 39 in the section "If a Manufacturer Is Not Following cGMPs, Are Drug Products Safe for Use?"
A. Okay.
Q. About two-thirds of the way down, it says: "The impact of cGMP violations depends on the nature of those violations and on the specific drugs involved."
Do you agree with that?

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A. I think it's poor wording.
I would have to say I agree with it.
Q. All right. The next sentence says: "A drug manufactured in violation of cGMP may still meet its label specifications."
Do you agree with that?
A. Of course.
Q. And the remainder of the sentence says: "And the risk that the drug is unsafe or ineffective could be minimal."
A. Of course.
Q. Do you agree with that?
A. Of course.
Q. So let me see if I state it another way, if I understand what these regs mean.
The finding of adulteration because of a cGMP violation at most reflects a possibility that out-of-specification drugs were produced; correct?
MR. MILLER: Object to form. Misstates previous testimony.
A. You can repeat the question. But I don't think it's correct. Would you repeat the question?
MR. MORIARTY: Can you read it back, please?

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(Requested portion is read.)
A. No. No, that is not correct.
Q. Okay. Adulteration is a regulatory definition; correct?
A. The FDA defines adulteration in the CFR.
Q. All right. And whether a particular drug is within or without its specifications is actually something you can test to determine; correct?
A. No.
Q. You can't?
A. No. What you can determine is that taking a sample, you have a certain level of probability if the product tests acceptably.
You have a certain level of probability and a confidence interval that the product is acceptable.
You don't know what you don't know. You haven't tested them all.
If you tested them all, and they were validated test methods, and they were a qualified individual that did the test, I think a fair assumption would be that all of them would be within specification.

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Q. All right. Well, let's just assume that in the 484 process, the FDA comes in and takes a sample of a solid oral dose product off a pharmacy shelf.
A. Sure.
Q. And tests a certain number of tablets for dissolution, assay, content uniformity within the United States Pharmacopeia guidelines.
A. Um-hum.
Q. Okay? And they are all within --
A. And in accordance to your submission.
Q. Yes. And they're -- and they're all within the USP parameters for that product.
A. Assuming it's a USP.
Q. Yeah. What is -- I mean, what is the confidence interval that the FDA would have regarding that particular tested batch?
A. Very low.
Q. Very low?
A. Yes.
Q. So why do they do it?
A. You have to ask them.
Q. And you've --
A. Because it will -- it would conceivably detect gross issues.

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When I say "gross issues," gross of the highest order.
Q. Have you ever been involved personally at J&J with the 484 process with the FDA?
A. Of the sampling process, no. If there was a non-conformance, I would have heard about it instantly.
Q. Have you ever seen in any of the material that you reviewed a final agency determination that Digitek, that single product, was adulterated?
A. I don't recall.
Q. Would you like to look?
A. No. It's too voluminous. We're trying to keep this within a day or two.
Q. Well --
A. I don't have the time -- I mean --
Q. It may be -- it may be time-consuming, but it's awful important for me to know.
A. I -- I will tell you that in reviewing the documents, I cannot recall an instance where they said -- specifically used the word Digitek is adulterated, separating that out.
Q. Okay. We typically take breaks every hour to hour and a half.

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You let me know when you're ready for the first break.
A. I'm fine.
Q. Okay. Do you know what the FDA's application integrity policy is?
A. No.
Q. Are you familiar with the CFRs pertaining to accuracy of documents like batch records, annual reports and things of that nature?
A. No, I'm not familiar with it.
Q. Well, what -- do you know anything about the F -- what the FDA would do to a company if it reasonably suspected that the company was falsifying data either in an NDA or ANDA or a run-of-the-mill record for production?
A. And you're asking me do I know anything about that?
Q. Yes.
A. Do I know anything? I know logic, that the -- it would be a serious offense, and I would assume criminal -- potential criminal prosecution.
Q. I didn't see anything in your report referring to any FDA 483s or warning letters about the integrity of Actavis's applications or data.
Did I miss a reference?

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A. No. You did not miss a reference.
Q. Did you -- do any of the references in your Appendix B contain FDA warnings or citations about data integrity regarding Digitek?
A. Could you repeat the question?
Q. Yes. In your Appendix B, this thing we've been talking about where you have all these --
A. Right. The references.
Q. -- things you referred to, do the 483s or warning letters or EIRs in your Appendix B contain FDA observations or findings about data integrity concerning Digitek?
A. I don't recall any.
MR. MORIARTY: Let's -- there's just a couple minutes left on this tape, so let's take our break now.
THE VIDEOGRAPHER: Please stand by. We are going off the record. It is 9:58 A.M. This ends Tape Number 1.
(Recess was taken.)
THE VIDEOGRAPHER: We are back on the record. The time is 10:12 A.M. This is the beginning of Tape Number 2.
Q. All right, Mr. Kenny.
Have you ever heard of Quantic

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Regulatory Services?
A. I've heard the name.
Q. Do you know anything about their reputation in the industry?
A. No. I really don't.
Q. Do you know anything about their reputation with FDA?
A. No. I have no idea. I know they're a consulting firm. And I believe they're rather large. That's it.
Q. Are you familiar with any Actavis batch record reviews done by Quantic Regulatory Services?
A. Specifically, no.
Q. And I didn't -- this is Exhibit 23.
(Exhibit 23, Letter dated 12/24/07 from Scott Talbot, was marked for identification.)
Q. First of all, are you aware that in the early 2007 FDA warning letter, they requested that Actavis get independent batch record review?
A. Yes. I'm aware of that.
Q. Have you ever seen Exhibit 23 before?
MR. KAPLAN: Do you have an extra?
MR. MORIARTY: I thought I passed one down.
A. When I look at the cover, I say no.

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I'm pretty sure I haven't seen this.
Q. All right.
A. It's a lot of blank.
Q. It's a lot of redactions. I understand that.
So -- first of all, you see that the cover of Exhibit 23 is a letter dated December 24, 2007 to a compliance officer at FDA from Scott Talbot, who was then site head of quality at Actavis Totowa; correct?
A. Correct.
Q. And then attached, I will represent to you that these are Quantic records regarding batch record review.
And, if you look at Bates page 1867202 -- I think you're -- you're on the same page -- on that page, Items 35 through 39 are specific Digitek batch records; correct?
A. It appears, yes.
Q. And then later, at Bates page starting 1867214 --
A. Okay. Sure.
Q. -- and spilling over into the next page, between Items 47 to 80, inclusive, are all specific Digitek batch records; correct?

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A. Yeah. Items 47, whatever you want to call it, through 80 are Digitek.
Q. All right. And have you seen the Quantic Regulatory Services protocol that they used for the review of the Digitek batches?
A. No, I did not.
Q. And I will represent to you that if you count them all up, they looked at 39 Digitek batch records.
Would you trust me on that?
A. I trust you implicitly.
Q. And do you know how many of those 39 were of what ultimately became recalled batches?
A. In 2007, no. I -- I couldn't determine that.
I'd have to look at the number of batches that were within expiration, is the only way I could tell.
Q. All right. I want you to assume that 19 of those 39 were of batches that were ultimately recalled.
Okay?
A. Okay.
Q. And go back to the cover page of 23.
A. Sure.

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Q. Actavis tells the FDA that Quantic's ultimate conclusion was: "On December 21, 2007, Quantic provided Actavis with a statement indicating the audit was complete, and the manufacturing and laboratory records have reliably confirmed the identity, strength, quality and purity of the marketed products."
Do you see that?
A. I certainly do.
Q. Do you have any basis on which to disagree with Quantic's assessment in that regard?
A. Well, I have to qualify this.
Q. Well, can you answer my question first? And then --
A. Do I have any --
MR. MILLER: Objection.
MR. MORIARTY: He can qualify it. I want a yes or no, and then he can qualify it.
A. Well, repeat it one more time, please.
Q. Do you have any basis to disagree with Quantic's conclusion regarding the 39 batches that they --
A. Yes, I would.
Q. Okay. What's the basis?
A. Can I reread this out loud? It says:

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"Quantic provided Actavis with a statement indicating the audit was complete, and manufacturing and laboratory records have reliably confirmed the identity, strength, quality and purity of the marketed products."

I would disagree with the word "reliably."

Q. Why?

A. Because they took a -- they looked at a batch record that indicated that there was no major issues, assuming there were no major issues, and if there were major issues, the batch would have been held and reviewed.

The assumption there is that the batch records contained accurate information. The assumption is that the test methods that were used were validated. The assumption is that the process is validated.

And if you form all the -- the assumption is that the equipment is calibrated. The assumption is that people are properly trained.

Now, if all of those things were in place, and then I looked at -- if I was Quantic, looked at the batch records, I would say, you know, they have a reliable process. They have reliable

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testing. Etcetera, etcetera. Based on all that reliable good stuff, I will say that, hey, I can say reliably, you know, this sample -- I'm sorry, this sample -- these batch records make me feel good about it.

Q. Okay. But if I'm correct, you've not only never seen Exhibit 23, and you've never seen Quantic's protocol, and you've only seen three batch records, compared to at least their 39; correct?

A. Yes.

Q. And I didn't see anywhere in your report that indicated that any process for Digitek was not validated. Have you made an observation --

MR. MILLER: Objection.

MR. MORIARTY: Let me finish my question.

MR. MILLER: Sure.

MR. MORIARTY: Then he gets to object. Then you get to answer it.

Q. I didn't see any observation in your report indicating that any process for Digitek was not validated.

Have you given that opinion in your report?

MR. MILLER: Object to form.

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You can answer.

A. Okay. The process that can produce defective product is not a validated process.

MR. KAPLAN: I'm going to object and move to strike that answer as not being responsive to the question you were asked.

THE WITNESS: Okay.

MR. MILLER: And continue on with the same answer.

He can object, but you can still continue on.

A. Okay. I don't -- I --

Q. What I'm asking is: I didn't see anywhere in your report to indicate that any Digitek process was not validated.

A. Okay. To answer your question specifically, I did not use the term Digitek in terms of a non-validated process --

Q. Okay.

A. -- specifically in here.

Q. Okay. Do you have any evidence that the FDA did not accept Actavis's and Quantic's findings as exhibited by Exhibit 23?

A. No. I have no evidence.

Q. That's Exhibit 24.

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A lot of paper.

A. Um-hum.

Q. And I'm not going to take you through all of it.

Now, in your Exhibit -- I'm sorry -- your Appendix B, I didn't see a reference to any FDA Form 484s.

A. That's correct.

Q. Did you review any FDA Form 484s?

A. No, I did not.

Q. Well, let's look at Exhibit 24.

(Exhibit 24, FDA Collection Report for Sample Number 377410, was marked for identification.)

Q. Is that for Sample 377410?

A. Yes.

Q. And if you look at the narrative, does it indicate that in February of 2007, FDA took two bottles of 100-count, 125 microgram Digitek from Actavis?

A. Could you point to where that is? Is it here?

MR. KAPLAN: It's on the first page, under "Description of Sample."

Q. If you go to page 3 of 3 of Exhibit 24,

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it says: "Method of Collection."
Do you see that?
A. Yes, I do.
Q. Okay. So here, they took 200-count bottles of 125 microgram Digitek from the firm's inventory. And then it gives the Actavis batch number; correct?
A. It appears to, yes.
Q. 70078 A1.
Do you see that?
A. Yes.
Q. And then FDA had an opportunity, presumably, to test as much of this as they wished; correct?
A. I presume yes. Sure.
Q. All right. And do you know whether or not they used United States Pharmacopeia testing standards for Digoxin?
A. I don't specifically know what they did.
Q. Have you ever looked at the USP reference standards for the monograph for Digoxin?
A. Not for Digoxin.
Q. Have you ever looked at the general USP standards for content uniformity?

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A. Yes.
Q. And assay?
A. Yes, sir.
Q. All right. But here, ultimately, based on whatever they tested, they say: "All methods are compendial and follow USP 29-NF24, page 704, Digoxin Tablets Monograph."
Do you see that?
A. Where?
Q. Under "Remarks" on page 3.
A. Yes. With the exception of impurity testing.
Q. Which they use a house standard; right?
A. "First in-house method is the limit test... utilizes relative retention times" -- yes. So they used USP methods, unless stated otherwise.
Q. And according to Exhibit 24, did all the samples that they tested from this batch passed -- pass?
A. I'm going to hunt for it. Maybe you can point to it.
Q. Yeah. I have to hunt myself.
A. I think it's a fair assumption to say they passed, or there would have been tremendous issues.

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Q. Okay.
A. I will accept that it says passed somewhere in here.
Q. All right. So what -- do you think that's significant at all?
A. Could you -- you know, could you define what you mean by -- be more specific in terms of "significant"?
Q. Well, first of all, do you know whether or not Batch 70078 A1 was among the recalled batches?
A. I -- since it was a 7, it probably was recalled.
Q. And as far as your opinions in this case, do you find FDA's testing and passing of a -- of a recalled Digitek batch significant at all?
A. Well, they don't test and accept. What they do is they test, they get acceptable results, and they don't react to it.
They don't accept anything. The FDA doesn't accept batches. They don't take that responsibility of accepting a batch.
They can get -- they can derive acceptable results. When they do -- let's say they do their surveillance program, and they take some of

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our product and they test it.
They don't find the batch acceptable. What they find is the sample that they tested met specification, and they have no cause for concern because it met specification. They don't accept or reject anything.
Q. I understand that. But --
A. You used that term "accept." That's all.
Q. Well, they -- do these results corroborate Actavis's testing of the same batch?
A. Do they corroborate?
Well, if -- if Actavis got acceptable results of their sample, the FDA took a small sample, presumably smaller than Actavis's, and they confirmed each other that the -- based upon only the testing that the product is acceptable. But the testing is only a small portion of determination whether a batch is acceptable.
Q. I understand that.
Isn't it likely, given the Actavis testing and the FDA corroborative testing, that the tablets in Batch 70078 A1 were within the USP specifications?
A. I can answer that.

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Is it probable? I would say that, based upon the fact that they do not have validated -- that in general, they do not have validated processes, based upon in general that 25 percent of the equipment is not proper -- not qualified, based upon the lax practices that are done in laboratories, etcetera, etcetera, I would only state -- and this, I am being 100 percent honest here. I'm not trying to, you know -- to, you know, avoid the question.

I would -- I cannot state that that batch is in compliance because my entire history of working in compliance is based upon systems working. It's not based upon samples. A sample is a merely confirmatory way of saying guess what, guys? At least we know the three samples that we tested were good.

Since they had significant issues with content uniformity in general, it -- it -- I lack the confidence that, in general, they -- they have well validated processes.

But I'm talking in general, not specifically to Digoxin. But Digoxin is part of this population, therefore...

Q. So, if I really understand what you

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just said at a global level --

A. Yes.

Q. -- you are assuming, because of general cGMP violations, that Digitek had some problems; right?

MR. MILLER: Object. Misstates previous testimony.

It's okay to answer.

A. Okay. I don't understand the word "problems," Digitek had some "problems."

Q. In your answer, I asked whether it was likely that the batch met USP specifications. You never said anything about that.

You said that, for a variety of reasons, you didn't think the batch was likely in compliance.

What do you mean by "in compliance"?

MR. MILLER: Object to form.

A. That the systems and procedures that are in place that -- that formed the basis for testing -- no -- formed the basis for determining acceptability of the batch, if those are faulty, and they've shown themselves to be having a lot of issues, I cannot make the assumption that taking samples from the FDA, taking samples from whoever -- I can't make the assumption that that product is acceptable.

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Q. All right. What do you mean by "acceptable"?

A. "Acceptable," meaning meets specification each and every time, each and every unit.

Q. Okay. What I'm trying to find out -- and let's go back to Exhibit 39. It says here: "A drug manufactured in violation of cGMP may still meet its label specifications."

And you agreed with me on that?

A. Yes. I agree with that.

Q. Okay. I want to talk about the labeled specifications.

A. Surely.

Q. Okay. First of all, have you seen any test results of any type to indicate that Batch 70078 A1 did not meet its labeled specifications?

A. I don't believe I have seen any information.

Q. All right. Now, can you please show me anywhere in all the material that you reviewed anyplace where the FDA said that Digitek did not have validated manufacturing or testing processes?

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A. Well, the 25 percent of the equipment was not qualified. It's in the 43. I think it was 2004, perhaps. That's a significant issue.

Q. Are you finished with your answer?

A. I certainly am.

Q. Show me anywhere in the material that you reviewed anyplace that said that any equipment used to make Digitek was not qualified.

A. I don't know what the blenders, etcetera that were used as examples of not being the correct IQ OQ, which is installation qualification, operation qualification and performance qualification.

I can't link those two between the manufacturing of Digitek and those particular pieces of equipment. I'd have to -- I'd have to do much more research.

Q. So sitting here today, you don't know that any Digitek equipment was found to be not qualified by the FDA; correct?

A. Yes. Based upon what I've reviewed.

Q. All right. Then let me go back to my first question, now that we've taken care of equipment.

Show me anywhere in all the material

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that you've reviewed, please, where FDA specifically says that there is a Digitek manufacturing or testing process that is not qualified or validated.

A. All right. The way I would answer that is that the only evidence that I have seen where a process is validated was done, I believe, in '93.

I glanced through it. And the reason I only glanced through it is whatever work was done in '93 is of -- of little use to batches produced 13, 14 years later. They may have done great work.

So I have yet to see any well-constructed validation studies. I will assume that between '93 and the production of these batches that they didn't do them because I haven't seen it.

Q. Well, there's a lot of things you haven't seen. But we'll get to that later.

Is there an FDA reg that says specifically that these processes have to be revalidated?

A. Is there a specific reg? I'd have to look at -- at 21 CFR.

Can I glance at it? I do have a copy.

Q. You have it among your materials?

A. No, I don't.

Q. I've never seen one, but perhaps you

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know of one.

A. It's in there someplace.

MR. MILLER: We had it out once -- once already.

Q. Well, FDA inspected Actavis on a number of occasions for a variety of reasons between 1998 and 2008, did they not?

A. 1998 and -- yes.

MR. MILLER: Matt, you asked him a question. And he wanted to answer if he could see the CFR.

MR. MORIARTY: I'm changing the question. I don't want to dig for the reg. Okay?

Q. They did inspect a number of times for a number of reasons over those 10 years?

A. Yes.

Q. And they had an opportunity to see and observe whether Digitek processes and equipment were validated or not validated; correct?

A. Correct.

Q. And even in 2008, when the focus was on a Digitek batch, 70924, FDA never said in the 483 in May of 2008 that Digitek processes and equipment were not validated, did they?

A. I believe that's accurate.

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Q. And you said something --

A. But they may not have looked for it. They didn't look for everything. They went in. What the FDA does, they look for examples. They don't look to do a comprehensive review.

Once they find examples, they make the assumption, and it's certainly a reasonable assumption, that that particular quality system is in violation of GMP.

They have found enough evidence so that you need to go back, as the manufacturer, the tester, to go back and do a comprehensive review of that quality system, since you've shown that it's unreliable, what you're doing.

You need to go back and do a comprehensive and then determine whether or not you're in compliance.

So, if it were me, and I found out, which would not happen, that I had 25 percent of my equipment that was not qualified, then I would go back personally and take a look at all those things, including process validation, which is the culmination of all of these development events.

MR. KAPLAN: With all due respect to the witness, I'm going to move to strike your last

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answer because you're not responsive to the question that Mr. Moriarty asked you.

THE WITNESS: It's not on purpose.

MR. KAPLAN: Then on purpose, if you would, listen carefully to his questions, and try to answer just the question that he asks.

THE WITNESS: I think I --

MR. MILLER: You've answered it perfectly, Mark. He's allowed to object. But you answered it perfectly, and keep going.

MR. KAPLAN: And I move to strike counsel's comments as inappropriate.

MR. MORIARTY: Can I go on?

THE WITNESS: In all fairness, I thought I did.

Q. What independent analysis did you do to determine whether Digitek manufacturing and testing processes were validated?

A. In -- in looking at, for example, the batch with the double-thick tablets, that particular -- the evidence that I was shown for that particular batch was horrendous.

It showed more errors than any batch record I -- I won't say I've ever seen. It ranks up there.

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The level of investigation as a determination of a, quote, validated --
Q. Excuse me.
MR. MILLER: No.
Q. I need to stop you. What I'm asking is not your overall opinion of their sloppiness or their GMP.
I want to know what independent analysis you did whether they were validated. Not whether they made mistakes or -- whether they were validated.
A. I'm trying to answer.
MR. MILLER: And I'm going to object. Excuse me, Mark. I think the answer did go to the question.
MR. MORIARTY: That's fine. Let him answer.
MR. MILLER: I'm going to let him answer, Matt.
Q. Go ahead.
A. Did I find -- one more time.
Q. I want to know what -- okay. You've already told me that nowhere in FDA's 483s or warning letters did they make a specific comment that FDA -- or Digitek processes were not validated

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or that Digitek equipment was not qualified.
What independent assessment did you do about validation? Not about GMP, about validation.
A. You mean a validation study?
Q. Yes.
A. The only thing that I read concerning Digitek was a 1993 process validation study.
Q. Okay.
A. That's it.
Q. All right. Now, among your answers earlier, you said that there were lax practices in the lab.
Can you show me anywhere in the material that you reviewed where FDA said that there were any lax laboratory practices regarding Digitek?
A. I'd have to look at the -- Digitek? I'd have to look at the -- all of the 483s, the EIRs. I'm sorry. I -- I don't recall.
MR. KAPLAN: That's what you did, didn't you?
A. I did, but I don't recall. I was -- my focus was not specifically only on Digitek.
My -- my focus is first to understand what kind of systems and procedures are in place. Is this a well-controlled company?

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Now, if --
MR. KAPLAN: I'm going to move to strike that as not responsive.
All he asked you was where did -- did you see any reference to lax laboratory practices re Digitek in anything that you reviewed? That was the question.
MR. MILLER: And he's entitled to give an answer.
MR. KAPLAN: Yes or no? Did you see any reference?
MR. MILLER: Let's answer his question before we get to your question.
A. I mean, I'm not trying to avoid the question. Understand, I'm not trying to avoid it. I don't recall any.
Q. Mr. Kenny, what I'm trying to do today is be very specific, okay, about Digitek and findings about Digitek by FDA or by you. Okay?
(Exhibit 25, FDA Summary Report for Sample Number 448881, was marked for identification.)
MR. MILLER: Thank you, Matt.
Q. Have you ever seen Exhibit 25 before?
A. No.

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MS. CARTER: Matt, real quick, I have a question about Exhibit 24 and 25.
Were these produced in -- in discovery?
MR. MORIARTY: We got these from the FDA pursuant to an FOIA request, just like you got most of your documents from the FDA pursuant to an FOIA request. These are not my company's documents.
MS. CARTER: Okay.
Q. Have you ever seen Exhibit 25 before?
A. No, I have not.
Q. All right. Is this Sample 448881?
A. Oh, I'm sorry. Yes.
Q. FDA 484 sampling?
A. Yes.
Q. Okay. And let's go -- if you go through here, you see that what FDA did was go to a Walmart pharmacy in Indiana and collect two 100-count bottles of Digitek 125 micrograms.
A. Okay.
Q. Is that right?
A. I don't see the Walmart part, but the -- I'll assume that what -- so they have samples. They collected them. Okay.
Q. Okay?
A. Yeah.

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Q. If you go to the second page, it says "Walmart pharmacy warehouse" down there.
Do you see that?
A. Please point that to me. "Low-cost generic" -- oh, yeah. Okay.
Q. And this was in December of 2007; correct?
A. Collection identification. Sample -- it says something EB 12307?
Q. Yes. December 12, 2007. The same month in which Batch 70294 was on hold; correct?
Do you know that?
A. I believe that's correct. Wait a minute.
Repeat the last part.
Q. This is the same month, by coincidence, that Batch 70924, the double-thick batch, was on hold for investigation; correct?
A. That is correct.
Q. All right. And what FDA did was, again, test pursuant to the United States Pharmacopeia methods. And all these samples passed all the tests to which FDA subjected them.
Is that correct?
A. I'm going to assume, because in here it

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says the lab -- the product specifications for identity, dissolution and content uniformity, product meets it.
Q. Okay.
A. That's on page 1.
So I am going assume, you know, not going through this thing, that they would have highlighted whether or not there were any non-compliances, non-conformances.
Q. And this was Batch 70298 A1.
Is that right?
It's in the middle of the second page, under "Manufacturer's Code."
A. Yes. 70298 A1, expiration April of 2009.
Q. Do you know whether this was a recalled batch?
A. I will make the assumption that it's recalled because of the batch number.
Q. Have you seen any test results of any type to indicate that tablets from Batch 70298 A1 did not pass USP testing?
A. As finished product test, no, I have not. As a finished product test.
(Exhibit 26, FDA Summary Report 448892,

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was marked for identification.)
Q. Handing you what's been marked as Exhibit 26.
MR. MORIARTY: Harvey.
MR. KAPLAN: Yes, sir. Thank you.
Q. We'll get good at reading these by the end.
A. I think we are getting better.
Can I circle things or not?
Q. Sure.
MR. MILLER: Is that on the -- you don't want to write on the -- on the copy that's being marked as an exhibit.
THE WITNESS: Oh, okay.
Q. There's the exhibit copy. You mark whatever you want on it.
December 3, 2007, FDA collected Sample 448892, again from a Walmart warehouse in Indiana.
A. Okay.
Q. The same day as the other -- as Exhibit 25.
A. All right.
Q. And this was 200-count bottles of .250 microgram Digitek; correct?
A. Yes.

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Q. From Batch 70664 A?
A. 70664 A1, correct.
Q. And this -- all these samples tested appropriately within the specifications?
A. Yes. It says: "The product meets specification for identity dissolution and content uniformity."
Q. Do you have any evidence, have you seen any evidence to indicate that tablets from that particular batch did not pass USP testing?
A. I have no evidence to suggest that it did not pass finished product testing.
Q. Had you seen this before, by the way?
A. No, I did not. I haven't seen any of the -- I can make a blanket statement. I have not seen those forms.
(Exhibit 27, FDA Collection Report for Sample 453913, was marked for identification.)
Q. Showing you what's been marked as Exhibit 27.
A. Okay.
Q. Does it indicate that in February of 2008, FDA took Sample 453913?
A. 45 -- right. Yes.
Q. Was it one 1,000-count bottle of 125

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microgram Digitek?
A. One. Correct.
Q. And it was from Actavis Batch 70737 A?
A. That's correct. A1.
Q. And did all the tests to which FDA subjected these tablets pass the USP criteria?
A. I'm trying to find the -- this is a little different.
I assume that somewhere, it has that statement.
Digoxin, reason for collection, description sample method, how prepared, identification, delivered, remarks. I don't see where it says that.
Wait a minute. Let's look in here. Continuation.
Okay. If you look on, I don't know, around the third page, page 1 of 1 -- looks like this.
Q. Yep.
A. Okay. It states that the -- where is it now?
Q. "The sample meets USP specifications for identification, content uniformity and dissolution"; correct?

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A. Correct.
Q. Have you seen any evidence to indicate that any samples from Batch 70811 -- I'm sorry -- from Batch 70737 A1 did not pass USP testing?
A. I see no evidence that the final samples that have been tested, they've all met finished product specifications.
(Exhibit 28, FDA Summary Report for Sample Numbers 454866, was marked for identification.)
Q. Handing you what's been marked as Exhibit 28.
This is February 15, same day as Exhibit 27, Sample 454866; correct?
A. 45 -- correct.
Q. And this was taken from a McKesson warehouse in Georgia?
A. Low-cost generic drug sample survey. I'm looking.
I suspect it's here.
Q. It's way at the back. Way at the back.
A. Oh, okay.
Q. The second page from the back. They just send us these out of order.
A. I understand.

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Q. See that? McKesson Drug Company?
A. Yes, I do.
Q. All right. And this sample also was subjected to USP testing for identification, content uniformity and assay, and it passed; correct?
A. Where does it say it passed?
Q. Go to the very first page, under "Lab Conclusion" --
A. Yes. Right. "The sample meets USP specifications for identity, dissolution and content uniformity." Yes.
Q. Ever seen any test results to indicate that Batch 70811 A had out-of-spec tablets?
A. I don't recall it. I would assume that no, I have not seen it.
Q. Do you know any of the other experts hired by the plaintiffs in this case?
A. I met Russ Soma. I've talked with -- met him at a -- do I know -- yes. Russ Soma.
Q. Just Russ?
A. Just Russ.
Q. Did you refer the plaintiffs' lawyers to Russ?
A. Yes, I did.
Q. Have you ever read an article written

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by one of the plaintiffs' experts named James Farley?
A. No. I don't know the name. But I've heard the name. That's all. I haven't read anything.
Q. He wrote an article. And I thought I had extra copies of it here. Let me just read you this, and you can tell me whether you agree with it.
He co-wrote this article with a lawyer about discovering the cause of a drug's defect. And it says: "Pre-filing investigation. When a client comes to you suspecting that he or she has taken an adulterated drug, you should tell the client to save the drug, the container and all labeling and packaging information."
Here's what I want to ask you about. It says: "Next, a laboratory must analyze the drug and test for its active pharmaceutical ingredient and for strength and purity."
Do you agree with that statement?
A. That they must or they should? I guess I --
Q. It says here "must."
A. I would say they should. Because it depends upon the sample and the condition of the

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sample and...
Q. Let's go to Exhibit 29.
(Exhibit 29, FDA Collection Report for Sample Number 452746, was marked for identification.)
Q. I assume you haven't seen this one either.
A. Correct. Yeah, we can assume I haven't seen any of these that look like this form.
Q. Okay. And here, we are looking at Sample 462746; correct?
A. Correct.
Q. Collected March 21, 2008.
Is that right?
A. Collected when?
Q. March 21, 2008.
A. March 26, 2008. Correct.
Q. And --
MR. KAPLAN: I think you were talking over each other. March 21, March 26.
A. It says March 26.
Q. All right. That's fine. And this is Batch 70834 A?
Oh, I'm sorry. Batch 70300 A.
Do you find that anywhere?

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A. I'm trying.
I see 56008 A.
Q. Do you see a different manufacturer's batch number than I just read?
A. Look at this. It appears that that is the lot number.
MR. MILLER: And for the record, when you say "this," perhaps we ought to --
THE WITNESS: Exhibit 29.
MR. MILLER: There was a lot number --
THE WITNESS: Yeah.
MR. MILLER: -- that you were referring to, I believe?
THE WITNESS: The only thing that looks like a -- looks like a lot number is 56008 A.
Q. All right. Look on the third page.
A. The third page.
Q. The middle says Lot 7P964.
A. Yes, it does.
Q. You see that?
A. Correct.
Q. And I will represent to you that that is Actavis Batch 70300 A, renumbered by UDL, which made these blister packages, as 7P964.
A. Which is not unusual.

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Q. All right. And FDA tested the same things, identity, content uniformity and assay, and all these specimens passed USP standards?
A. Meets specs. That's correct.
Q. Do you have any evidence to indicate that there are tablets from Batch 70300 A that do not meet the USP specifications?
A. No. I have no evidence.
(Exhibit 30, FDA Collection Report for Sample Number 462753, was marked for identification.)
Q. Here is Exhibit 30.
Is this another FDA 484 sample report?
A. Correct.
Q. Sample 462753, also collected March 2008.
A. 2008? I'm sorry. Would you repeat the lot number?
Q. I haven't said the lot number. I said the sample number and when it was collected.
A. Correct. That is correct.
Q. And my notes indicate that that's from Batch 70834 A.
A. This has another, I guess, 8A332 on this page.

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Q. I want you to assume that it is Actavis Batch 70834 A.
A. Surely.
Q. Did this -- did the specimens tested by the FDA meet the specifications for identification, dissolution and content uniformity?
A. On page 1 of 1, the fourth page, it states that: "Lab Conclusion: Meets specs for identification, dissolution and content uniformity."
Q. Do you have any evidence to indicate that tablets from Batch 70834 A did not meet those specifications?
A. I have no evidence.
Q. Are you aware of any occasion in which FDA did a 484 sample and found Digitek that didn't meet the specifications under the USP?
A. I have found no exceptions.
Q. And I want to go through these quickly, because we -- I will represent to you that the older FDA has these documents, the less weighty they become.
(Exhibit 31, FDA Summary Report for Sample Number, was marked for identification.)
Q. So Exhibit 31 is another 484 sample set; correct?

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A. Correct.
Q. And it says here that this was Batch -- well, this was -- this sample was taken in 2002; correct?
A. 2002. March 25th.
Q. All right. And it passed the USP requirements for dissolution?
A. Correct. "Meets USP uniformity of dosage units spec."
Q. And then lower, it says it meets the dissolution specs?
A. "Product meets USP requirements for dissolution at Stage 1."
Q. All right.
(Exhibit 32, FDA Summary Report for Sample Number 157504, was marked for identification.)
Q. Exhibit 32 is another Form 484 from the FDA for a sample also taken in 2002; correct?
A. Yes.
Q. Did the -- did the product, as tested by FDA, meet the USP specs?
A. Yes, it did.
(Exhibit 33, FDA Summary Report for Sample Number 178890, was marked for

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identification.)
Q. Exhibit 33. Is Exhibit 33 another 484 from the FDA?
A. Yes.
Q. Does it indicate that they took a Digitek sample in 2002?
A. Yes.
Q. And it passed?
A. They have conclusion --
Q. Actually --
A. It doesn't say anything.
Q. Okay. If it didn't -- well, here on the right, it says "In Compliance," does it not?
A. I don't know what that means.
Q. All right. If -- if it was found to be out of spec, you would have expected to see some evidence of that?
A. I would -- I would presume that. I think it's a fair assumption.
Q. And the last one of these is Exhibit 34.
(Exhibit 34, FDA Summary Report for Sample Number 178891, was marked for identification.)
Q. Is this another Form 484 from the FDA?

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A. Oh, yes. I'm sorry.
Q. And tested Digitek?
A. Correct.
Q. And like the last one we looked at, it says "In Compliance" in two different places?
A. Yes.
Q. Do you see any evidence that it didn't pass?
A. I see no evidence. It's in compliance.
Q. At least in the eyes of the FDA, do you believe that these kind of 484 results provide some assurance to them that the product itself is meeting its labeled specifications?
A. I would say that all testing that meets specification provides added information, yes.
Q. Well, I asked whether it provided FDA assurances that the product was meeting specifications.
A. It provides a certain level of assurance.
Q. Does it also provide some level of assurance to FDA that its tests are corroborating the finished product tests performed by Actavis on these batches?
A. If I make the assumption that Actavis

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test results are acceptable, then I would say your statement is correct.
Q. All right. You looked at the annual reports --
A. Correct.
Q. -- did you not?
A. Yes, I did.
Q. Did you find any instances of finished product, either assay or content uniformity, that were outside the specifications, the USP specifications, in the annual reports that you reviewed?
A. I'd have to go back to the annual reports to say.
Q. Okay.
A. Which I have available, if you would like me to.
Q. First of all, if they were out of spec, would you have expected there to be investigations?
A. Most certainly.
Q. Would you have expected there to be FDA regulatory inquiries?
A. Not necessarily.
They do sampling. They don't -- they don't do a comprehensive review of every annual

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product review and every batch record. They do a sampling.
Q. Okay. Well, in your report, did you note anywhere that there were out-of-specification finished product test results contained in any annual reports?
A. I'd have to do more research on Lots 80224 A1 and 80227 and 80228 A1, because there's some records indicating that these batches were not acceptable. They had high weights. Both of -- all three of those batches, according to records, says it has high weights. I have not seen the batch records.
Q. Do you know how many of those batches were rejected and not sent to Mylan for distribution?
A. I would assume that none of the rejected batches were sent to Mylan.
Q. Well, do you know specifically of those three how many of them were rejected?
A. No. I'd have to go back through the records.
I am going to make the assumption that they were rejected. I think that's a fair assumption. The company is not going to release

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based upon out-of-specification results to the market.
I mean, I don't know if that's a fair assumption, but I'm going to assume they --
Q. Well, let me get back to my -- my question.
Did you note -- did you make comments in your report, which is long -- I mean, 35-some-odd pages -- about any out-of-specification results on batches that were sent to the market for finished product testing?
A. That was sent to the market?
I'd have to -- I'd have to go back through the history of these batches to see if they were released. I can -- I can think of no example at this particular point.
MR. KAPLAN: Again, I'm going to move to strike his last answer as not responsive.
He said in your report, did you make any comments?
A. Oh, in my report? Well --
MR. KAPLAN: No. In your report, did you make any comment on any out-of-spec batches that were sent to the market? Did you? Yes or no?
A. I can't answer it that way.

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Did I make a remark? No. But I can't tell you, without investigating these three batches, whether they went to the market.
Q. Okay. Now, we've looked at all these testing by FDA. All right?
A. Yes.
Q. And let's just take the batches that FDA tested.
A. Okay.
Q. All right?
A. Yes.
Q. Just those.
If somebody assumed that all of the tablets in a particular batch were outside the USP specifications, this FDA testing proves that that is an incorrect assumption.
Is that right?
A. That is correct.
MR. MORIARTY: I need to look for an exhibit.
Q. I'll give you the flattest one.
This is Exhibit 35.
(Exhibit 35, Celsis Report, was for identification.)
Q. Do you see that?

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A. Yes.
Q. This is captioned, on the first page, "Celsis," C-E-L-S-I-S, "Analytical Services."
Do you see that?
A. Yes.
Q. Are you familiar with Celsis Analytical Services?
A. No, I'm not.
Q. Have you reviewed Exhibit 35? Is it listed in your --
A. No.
Q. -- Appendix B?
A. I have not reviewed it. It is not listed.
Q. In the depositions of the Mylan or UDL employees that you read, did you see that, from time to time, UDL sent product out for USP testing?
A. Yes.
Q. And, on some occasions, they did that just to -- for example, because when they repackage, they need to test dissolution and whether their repackaging is going to affect the stability of the product; correct?
A. I don't know why they sent it to UDL.
Q. All right. Did you see an instance in,

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say, any of the Mylan depositions where UDL sent material out to be tested because FDA was concerned about product quality?
A. Not specifically.
Q. Well, I will represent to you that Exhibit 35, which is rather thick, contains testing done at the behest of UDL, sent to Celsis laboratories on a number of different occasions. And in each instance, the Digitek they sent passed the tests to which it was subjected.
Do you have any reason to believe that that did not happen?
A. I have no reason to believe, but I'd like to read it in order to answer that, if it's okay.
I'm not going to -- I just want to read something.
Q. Go ahead.
A. Can I write on this?
Q. Yes. We have extras.
A. It may be a question mark or something like that.
I can't read this. It says: "No less than 60 percent in 30," and they scribbled out "percent."

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In order to confirm this, I'd have to go to the product specification that this is the correct specification.
Q. You mean 90 to 110 percent?
A. No. I'm assuming that's correct. That's typical, but not necessarily correct.
Q. Well, let -- let me rephrase it, because this is a very long document.
At any point in the Mylan employee depositions, did anybody bring to the attention of those Mylan employees who were being questioned out-of-specification Digitek results from any testing that UDL had sent to Celsis laboratories?
A. I -- I don't know, but I don't recall seeing anything.
MR. KAPLAN: Would you read back the last question and answer, please.
(Requested portion is read.)
Q. Okay. Let's shift to Exhibit 69.
(Exhibit 69, UDL Laboratories Receiving Form, was marked for identification.)
A. Okay.
Q. Have you ever seen Exhibit 69 before?
A. It does not look familiar.
Q. And attached to all this is documents

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regarding a shipment of Digitek that was sent to UDL by Mylan and originally by Actavis; correct?
A. Yeah. I apologize. I was looking at the specification here of 90 to 105.
But could you repeat the question?
Q. Well, the documents have to do with a batch of Digitek that was sent to UDL; correct?
A. No. But I thought I saw here between 90 and 100 is the spec and -- oh, 110. And here, I'm seeing the 90 to 105.
Q. Okay. Could there be different specs for different tests?
A. Not for assay.
But it could be different products. This is .25.
May I look at the other document?
MR. MILLER: Certainly.
THE WITNESS: That one. I think it's on top.
A. These are .25, and it says 90 to 110.
This is .25, and it says 90 to 105.
Q. Do you know whether -- go ahead.
A. So one is incorrect.
Q. Do you know whether FDA ever changed or USP ever changed the testing specs?

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A. I don't know, but it's highly unusual.
Q. Have you ever seen any Celsis laboratory or UDL documents which indicate that Digitek samples tested by Celsis were ever out of specification, according to the USP specs?
A. I don't recall seeing anything.
Q. All right.
Do you have an opinion as to whether or not any consumer ever received a tablet that was outside -- let me rephrase that. Let me withdraw it and rephrase it.
Do you have an opinion, to a reasonable degree of probability, as to whether any consumer ever received a tablet of recalled Digitek that was normal in size but outside its USP specifications?
A. Do I have a concern? Yes.
Q. That's not what I asked.
A. You have to rephrase it.
Q. Let's stop. This is a very specific question.
A. Sure.
Q. Do you have --
A. I'm trying to answer it as well as I can.
MR. KAPLAN: Listen. Just listen to

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his question.
Q. It's a very specific question.
Do you have an opinion, to a reasonable degree of probability, as to whether any consumer received a Digitek -- recalled Digitek tablet that was normal in size but outside its USP specifications?
A. Not within a reasonable probability.
Q. All right. Are you a -- do you have any expertise in statistics?
A. I have knowledge of it.
Q. Do you have expertise in it?
A. No. I would not say I'm an expert.
Q. Do you know anything about statistical significance?
A. I have some knowledge of it.
Q. All right. Do you have an opinion as to whether 4 1/2 percent -- let me rephrase that question.
FDA tested 7 of the 152 recalled batches --
A. Okay.
Q. -- independently in these 484s that I have had marked as exhibits.
By my math, that's 4.6 percent.

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A. Okay.
Q. Okay?
Is their testing statistically significant?
A. I don't know without taking a look at a statistical table.
I will say that it appears like a -- a sample that had a 95 percent confidence interval would approach what would be considered a statistically significant sampling.
Q. All right. Celsis labs, by --
A. But I would have to pull 105E, or whatever.
Q. What's 105E?
A. It is a military standard that's used throughout industry for sample -- sample inspections.
Q. You mean the one that nobody can read and understand?
A. No. I can read and understand it.
Q. You may be the only person on earth.
Have you used 105E in your work?
A. Yes. Not recently, but yes.
Q. Is it reliable or considered to be reliable?

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A. It's considered to be statistically accurate, yes.
Q. Okay. Celsis, by my calculations -- please assume I'm correct -- independently tested at UDL's request what turned out to be 11 out of the 152 recalled batches.
A. Okay.
Q. Which is 7.2 percent.
A. Okay.
Q. Is that statistically significant?
A. I don't know. I would have to take a look at the tables. It does approach the number that I would anticipate would be in 105E.
I'm not trying to avoid it, but I don't know that number. I'd have to take a look at --
Q. That's fine. I understand. I told you early on if you don't know the answer to my question, I want you to tell me you don't know.
A. I don't know.
Q. I don't want you to guess.
A. I don't know.
Q. Now, if we eliminate any overlap between FDA testing and Celsis testing -- let's assume that that is 16 of the 152 recalled batches.
A. Um-hum.

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Q. Which is about 10.5 percent.
Okay? You with me?
A. Yes.
Q. That would be statistically significant, wouldn't it?
MR. MILLER: Object to form.
Go ahead. You can answer.
A. 105E, all sampling is intended to be a proactive sampling. It is intended to take a look at a distribution of homogeneous product.
Based upon the sampling, based upon your acceptability, your AQL, you determine what the sample size is.
So, basically, it goes down to how many samples are you willing to say are unacceptable in -- in whatever sampling population you did?
You don't back into it by taking samples and keep your fingers -- keep sampling until you find something that's potentially rejectable.
That's not a statistical sample. A statistical sample is a proactive, is an experimental plan, and it's based upon probability charts.
Q. Were the Amide and then Actavis blend uniformity sampling plans contained in the ANDA?

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A. I don't know. I'd have to look at the ANDA.
Q. Were they contained in every batch record?
A. Could you repeat the question?
Q. Were they contained in every batch record?
A. What --
Q. One uniformity sampling plans.
A. One uniformity sampling plans, were they contained in -- in the batch records? That's correct.
Q. So the number they took and where in the blender, etcetera; correct?
A. Yeah.
Q. All right. Now, so FDA had every opportunity to comment on those in their analysis of the ANDA or if they ever looked at batch records; correct?
A. Yes.
Q. And Quantic Regulatory Services had that same opportunity, at least as to the 39 Digitek batches they reviewed; correct?
A. That's correct.
Q. All right. Now, I don't want to talk

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about blend uniformity out of specs. I just want to talk about the sampling plan.
Have you seen any evidence in any FDA document in which the FDA observed, cited or warned Actavis about the sampling plan itself for blend uniformity?
A. FDA? No. I saw nothing.
Q. Okay. Now, you know that during batch production of solid oral dose, operators in QA were taking a certain number of tablets for thickness, hardness, appearance and weight; correct?
A. That's correct.
Q. And those sampling plans were in the ANDA and every batch record; correct?
A. They are in the batch record. I'm not sure if it's in the ANDA.
Q. And did you ever see, in any FDA document, where FDA observed, criticized or warned Actavis or Amide about the number of tablets that they sampled in that manner in process?
A. I don't recall.
Q. And then lastly, and then we have to stop to change the tape, the finished product testing, you know, how many they take for content uniformity, how many they take for assay, etcetera,

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was all in the ANDA and the batch records; correct?
A. It's in the batch records.
I can't tell you what's in the ANDA.
Q. Did you ever see any FDA criticism in any of the documents that you reviewed of the number of samples that Actavis took to test assay or content uniformity or dissolution or stability in --
A. In the sampling, no, I did not.
MR. MORIARTY: Let's take a break because of the timing.
THE VIDEOGRAPHER: Stand by. We are going off the record. The time is 11:29 A.M. This is the end of Tape Number 2.
(Recess was taken.)
THE VIDEOGRAPHER: We are back on the record. The time is 11:35 A.M. This is the beginning of Tape Number 3.
Q. Before that short break, we were talking about sampling plans.
First of all, have you referred to any literature in your Appendix B about sampling plans?
A. I don't recall. I don't think so.
Q. And I don't recall seeing anything in your report critical of my client's in process or finished processed sampling plans.

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Is that correct?
A. Not 100 percent correct.
Q. Why not?
A. I put in -- I put in there, or I put in the report that as part of issues, non-conformances, out of specifications, situations where high risk could occur, I saw no evidence that they attempted to take a look at the sampling plan to increase the confidence that the product leaving the door didn't have problems.
Q. In your opinion, to a reasonable probability, are any of my client's blend uniformity, in process or finished processed sampling plans negligent?
MS. CARTER: Objection to form.
Q. For Digitek. For Digitek.
A. I would say their proactive plans, I saw no -- no issues. I think they were valid sampling plans.
Q. All right. I forgot these before when I was asking you about the FDA and their testing of Digitek.
Do you know what the batch certification program was way back when, in the '80s and '90s?

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A. I heard the term. I'm not familiar with it.
Q. That's when, for some drugs, FDA had to test and approve the release of batches before they could go to market; correct?
A. I don't know if that's correct.
(Exhibit 4, Letter dated June 8, 1995 to Shah from Department of Health & Human Services, was marked for identification.)
Q. Have you ever seen Exhibit 4?
A. No, I have not. 1995?
Q. This is a letter from FDA to then Amide indicating that these nine batches of Digitek passed their testing and could be released to market; correct?
A. That's correct. This 1995 document, yes.
(Exhibit 5, Letter dated July 20, 1995 to Shah from Department of Health & Human Services, was marked for identification.)
Q. And here is Exhibit 5. Is this a letter -- first of all, have you ever seen this before?
A. No, I have not.
Q. Is this a letter from FDA to then Amide

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indicating that they were exempt from the batch certification program?
A. That's what it states.
Q. And wouldn't FDA only do that if they had a high degree of confidence that the process was validated and in control?
A. I believe that's correct.
Q. Okay. Do you know how many people in the United States were prescribed Digoxin between 2006 and 2008?
A. No. I have no idea.
Q. Do you know how many prescriptions were written for Digoxin products between 2006 and 2008?
A. I have no idea.
Q. Do you know how many people were taking Digitek between 2006 and 2008?
A. I have no idea.
Q. Have you ever done the math to figure out how many tablets were affected by the Digitek recall?
A. How many tablets were affected? No, I have not.
If you figure there's 5 million tablets, and go through the number of lots, and multiply it out --

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Q. It would be --
A. -- millions.
Q. -- about 688.2 million.
A. Okay.
Q. Approximately. Is that correct?
A. If you say so. You've done the math.
Q. If you go by the theoretical batch size of 4.8 or 4.2.
A. Okay.
Q. Correct? Depending on the dose size?
A. If your math is right. And I have no reason to believe it's not.
(Exhibit 36, Recall -- Firm Press Release, was marked for identification.)
Q. This is Exhibit 36.
I believe you've seen this.
That's in your --
A. Yes.
Q. -- binder, isn't it?
That's the recall press release?
A. Well, it might not be in my binder because I looked at it electronically.
Q. Is it the recall press release?
MR. KAPLAN: Is there an answer to that question?

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THE WITNESS: I'm briefly looking through it.
MR. KAPLAN: The question is simply: Is that the recall press release?
THE WITNESS: This is a -- yes. Yes. It appears to be, yes.
Q. And it's Tab -- or it's Reference Number 59 in your Appendix B, is it not?
A. Yes.
Q. Now, it indicates generally in here that the recall is due to the possibility that tablets with double the appropriate thickness may have been commercially released.
Do you see that?
A. Yes.
Q. Is there anywhere in Exhibit 36 that indicates that this recall was about tablets of normal size with varying levels of deactive pharmaceutical ingredient?
A. Well, yes. Double strength. It varies by two.
Q. Let's -- let's read that again and ask my question again.
It says: "The voluntary all-lot recall is due to the possibility that tablets with double

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the appropriate thickness may have been commercially released."

Do you see that?

A. Yes.

Q. My question is this: Is there anything in this FDA-approved press release that indicates that this recall was about normally-sized tablets with varying levels of the active pharmaceutical ingredient?

A. Normal size, no.

Q. All right. In your opinion, Mr. Kenny, is double thick a different problem than normal size with varying active pharmaceutical ingredient?

A. Could you repeat the question again? I'm trying to answer that clearly.

Q. Sure. You were in the pharmaceutical business with J&J for 30 years; right?

A. Yeah. On and off.

Q. Okay. You know what investigations are all about; correct?

A. Most certainly.

Q. And you know generally how to manufacture, blend manufacture tablets?

A. In general, correct.

Q. All right. If somebody came to you,

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either at J&J or now in your consulting work with SpyGlass, and said we've got a problem with double-thick tablets, you would design an investigation about that; correct?

A. I would assist them, if asked.

Q. Okay. And I assume that what you're looking for is some sort of a cause --

A. Correct.

Q. -- of what would make double-thick tablets; right?

A. Right.

Q. And, obviously, it's a size issue. At its core, it's a size issue; correct?

A. There is a -- it's -- I guess I would say yes.

Q. All right. And then, by virtue of size, you'd want to know what -- is it too many excipients with normal pharmaceutical ingredient levels, or is it double the active pharmaceutical ingredients; right?

A. Right. You'd want to know the -- whether or not the content uniformity was correct.

Q. Right.

A. And if you made -- did an investigation and said content uniformity is correct, then it

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would probably pinpoint you to a tableting press, and you'd say that it is a physical issue.

Q. All right. Now, but on the other side of the equation, if somebody at J&J or in your consulting business with SpyGlass said we have a problem with -- our tablets are normal in size, but the active pharmaceutical ingredient is varying all over the place, your investigation would potentially take a different course; correct?

A. Of course.

Q. And the root cause might be completely different from the first scenario; correct?

A. It is a possibility it could be completely different, yes.

Q. And that is a distinction that the FDA would clearly recognize; is it not?

A. I don't know. I can't speak for them.

Q. Have you seen any document to indicate that the Digitek recall was about anything other than the double-thick tablet investigation that grew out of Batch 70924 A?

A. Stated as such, no.

(Exhibit 38, FDA Website Statement July 2009, was marked for identification.)

Q. I've handed you what's been marked as

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Exhibit 38; correct?

A. Correct.

Q. Have you ever seen that before?

A. Yes, I have.

Q. This is a statement on an FDA website from July of 2009.

Is that right?

A. Where do you see 2009?

You printed it on 6/15/2010.

Q. Which means it's still on the FDA website this month; correct?

A. I believe that.

Q. Do you know when they initially posted this?

A. I have no idea.

Q. And it's a -- it's entitled "Facts and Myths About Generic Drugs."

Do you see that?

A. I certainly do.

Q. And down about halfway on the first page of this exhibit, it says: "Recently, some misinformation has raised concerns over generic drugs. Below are some common myths in circulation."

Did I read that correctly?

A. Halfway down? Please show me.

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Q. There or there.
A. "Recently, some misinformation" -- yes. "Below are some of the common myths in circulation."
Q. Go to the second page, please.
The first full section on the second page says: "Myth: There are quality problems with generic drug manufacturing. A recent recall of generic Digoxin, called Digitek, shows that generic drugs put patients at risk."
Did I read the myth correctly?
A. I believe you did.
Q. And then it says: "Fact: FDA's aggressive action in this case demonstrates the high standards to which all prescription drugs, generic and brand name, are held."
Did I read that correctly?
A. Yes, you did.
Q. Now, let's go down to the fourth bullet point, the second sentence in the fourth bullet point.
"In our best judgment, given the very small number of defective tablets that may have reached the market and the lack of reported adverse events before the recall, harm to patients was very unlikely."

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Did I read it correctly?
A. Yes, you did.
Q. Do you disagree with the FDA's statement in this website?
A. Yes, I do.
Q. What's your basis for disagreeing with the FDA's conclusion in this regard?
A. Okay. There is, at least in my industry, a generally-accepted term, or at least concept, that you only receive a small portion of the actual adverse reactions, general complaints, regardless; that either the people don't realize that they had a problem, they're lazy, so that people have quoted 1 in 20 people will actually complain.
On consumer products, it could be slightly higher. There's an 800 number they call up and get a free product.
People don't even understand how to complain, if you will.
So I would not agree with that statement.
Q. So the part that you're focusing in on is what the FDA said here about the lack of reported adverse events before the recall?

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A. Correct.
Q. When you were with J&J, were you in pharmacovigilance?
A. No.
Q. Are you a pharmacovigilance expert?
A. I am not.
Q. When you consult for SpyGlass to your current clients in the last six years, do you consult in pharmacovigilance?
A. I -- I consult indirectly to that.
I look at complaints. I look at adverse events. I look to the investigations that they performed. I determine whether or not their investigations are adequate.
I make a clear determination, based upon looking at, over the -- just the last year, hundreds of adverse reactions and complaints as to whether or not I felt, in my opinion, they were adequately investigated.
So I will tell you, as part of the pharmacovigilance process, that is my role I've been asked to perform.
Q. Have you seen any evidence in this case that there were reports of harm to Actavis regarding Digitek prior to the recall that were not reported

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to the FDA at all?
A. I have seen no evidence in that regard at all. I haven't seen any reports of adverse events. I have seen no complaint investigations, other than 3611A.
So I -- I can't answer that because I haven't seen anything.
Q. All right. Let me break the FDA's website statement down in phrases.
A. Okay.
Q. They say: "In our best judgment, given the very small number of defective tablets that may have reached the market."
Do you agree with them when they make that statement?
A. I don't know how they can say the number is very small. They don't know.
Q. And you don't know either, do you?
A. Of course not.
Q. Okay.
A. But if somebody makes a determination that's counter to my experience, I can't make that -- say the number is very small. I can't say there's none. I can't say that there are a lot.
I think, based upon this type of -- in

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this context, you know, I'm not trying to be difficult, but I couldn't say that.
Q. All right. The last statement that they make, "harm to patients was very unlikely," do you agree with that?
A. I have -- this is clearly going beyond my own expertise.
Q. Well, just statistically, if you don't know the number of defective tablets that may have gotten out, you have no way to quantitate the potential harm to consumers, do you?
A. I am not involved in harm to consumers. I'm involved with the manufacturing process. I'm involved at the compliance level. I'm involved with adequate investigations. I'm involved with annual product reviews. That's the extent.
Anything -- if I start going into the field and determine whether something's safe or not, I've gone beyond my own expertise. And that would be irresponsible.
Q. Do you have any idea what percentage of pharmacies still hand-count out tablets when they fill prescriptions?
A. I have no -- no idea.
Q. Do you have any opinion, from a

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pharmacy point of view, as to how easy it would be, relatively speaking, to detect a double-thick Digitek tablet?
MR. MILLER: Object to form.
A. I would have no idea.
Q. If you wanted to scientifically determine whether double-thick tablets -- let's just leave it at that for now -- ever actually got to consumers, would you look at batch records about the weighing and measuring of tablets?
A. Most certainly.
Q. Would you ask consumers to have their tablets weighed or measured?
A. Ask consumers? I don't believe so.
Q. Okay.
A. Let me answer that accurately. What do you mean by "ask consumers"? I am not involved with asking consumers.
Q. That's fine. We're in the context of a litigation --
A. Okay.
Q. -- where the population on one side is a discrete number of people who claim they got defective tablets. Let's continue to stick with double thick.

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A. Okay.
Q. Among the people who still had tablets left over, the weighing and measuring of them with micrometers and sensitive scales is not a difficult process, is it?
A. Weighing -- no.
Q. And if you wanted to investigate, like Professor Farley's article said, weighing and measuring could be done; correct?
A. Yes.
Q. And you would want to look to the instances of customer complaints made to either the distributor or to Actavis itself about double-thick tablets found by consumers, would you not?
A. I would look at that and other potentially related adverse events and -- I would look at the entire picture. I would not just limit it to this one situation, because it could be -- it could be a compounded -- a confounded issue based upon things that I don't know.
So you look at everything because you don't know what you don't know.
Q. Okay. Well, let me ask: First, with regard to recalled Digitek, have you ever seen anything in any of the material that you reviewed

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that a pharmacist or a consumer has reported an actual tablet that is outside its size or weight specifications?
A. I -- I don't believe that I've seen it.
Q. Okay. So I've asked you that. An hour or so ago, I asked if you have seen any evidence that there were tablets of normal size with outside the USP specifications for active pharmaceutical ingredient.
And you said you hadn't seen any of those either; correct?
MR. MILLER: Objection to form. Misstates previous testimony.
A. You know, it's interesting, based upon the fact --
MR. KAPLAN: Wait, wait.
THE WITNESS: I'm sorry.
MR. KAPLAN: You started -- you started making a comment. You are not responding to the question. Please refrain from that.
THE WITNESS: I want to answer his questions, sir.
Q. Have you seen any tests from consumers or otherwise --
A. Okay. Are returned samples from

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consumers?
Q. Returned samples from consumers or tests that consumers have of samples that they kept or tests done by the FDA or anybody else to indicate that there are normal-sized tablets outside the specification --
A. I haven't seen any tests.
Q. Okay.
A. So I can't see any tests that are out.
Q. All right. So do you have any evidence at all that Digitek, outside its labeled specifications, reached consumers in this litigation?
A. Please, this is an important question. Repeat it.
MR. MORIARTY: Read that one back, please.
(Requested portion is read.)
A. I have no evidence.
Q. Do you know what a red herring is?
A. I think I do.
Q. Do you know plaintiffs' lawyers in this litigation said, in court and in court documents, that the double-thick theory is a red herring?
MR. MILLER: Object to form.

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A. I'm not familiar with that.
MR. MORIARTY: What was wrong with the form of that question, Pete? Because I'd really like the opportunity to correct it.
MR. MILLER: Well, it's vague.
What -- what attorneys? He's worked with several attorneys. And it's -- I think the term "attorneys" is broad and vague.
If you want to put the who into it.
MR. MORIARTY: Your colleagues in the PSC.
He said he wasn't aware of it, so I don't need to get more specific.
Q. Can you point me to any FDA 483 warning letter or EIR in the material that you reviewed that specifically indicates that they found Digitek tablets of normal size with varying amounts of the active pharmaceutical ingredient?
A. That were released?
Q. Yes.
A. I don't recall any instances.
Q. Okay. Can you show me in any of the material you reviewed any statement by the FDA that they found normal-sized Digitek tablets -- okay. I'll withdraw that question.

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When you say "released," you mean released to a distributor to go to market; correct?
A. Once you let -- once you say it's released in your SAP system, it's released, because it's out of your control at that particular point. That's what I mean by "released."
Q. Does the ANDA have a section that contains the actual pharmaceutical product formula for Digitek?
A. Yes, it does.
But I will say I am and most quality assurance people are not experts at the ANDA.
What we are, is we are experts once that -- once that -- once -- the ripple effect, if you will, somebody in regulatory and development has taken that and translated it into a specification. When it becomes a specification, then quality assurance people are involved.
Q. Okay. But in general, from what you know, is the pharmaceutical formulation, the recipe, if you will, contained in all the batch records?
A. In the batch records? Yes, it is.
Q. So FDA presumably has had an opportunity to look at the ANDA and all these batch records, if it looks at them, to see what the

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formula is about; correct?
A. I don't know what they looked at.
Q. All right. And in order to start the process off right, you have to mix the ingredients appropriately and in their appropriate proportions; correct?
A. That is correct.
Q. One potential root cause of tablets outside their active pharmaceutical ingredient specs would be if they mixed it wrong initially by putting in either too much or too little API.
Is that right?
A. Yes.
Q. Have you seen in the material that you reviewed any citations, warnings by FDA upon Actavis or Amide for problems related to following the formula appropriately and putting in the proper amount of API?
A. I do not recall a single instance.
Q. All right. And typically, the actual mixing of the ingredients in its proportions is done by one person and then verified by a second.
Is that right?
A. That's the way it's supposed to be done. Correct.

Q. Did you see any batch record that indicated that the company did not follow the appropriate formula?
A. No.
Q. If by chance, purely hypothetically, the company wanted to -- any pharmaceutical company wanted to cut corners and save costs, they would put too little API in the batch as opposed to too much; correct?
A. Sir, it is illegal to vary from the batch record.
If you are assuming that somebody was totally unethical, then they may put that in. I can't speculate on somebody who is totally dishonest.
Q. All right. And you've seen nothing in here, in the material you've reviewed, to indicate that anyone at Amide or Actavis was totally dishonest in the manufacturing of Digitek; correct?
A. Correct.
Q. Are you aware that --
A. Can I qualify that?
I don't know how I would understand whether they were honest or not.
I guess I would say that it's a

question that nobody can answer.
Q. Okay. Are you aware that in the process of making a solid oral dose, the raw materials are weighed at the beginning of the batch to assure that it complies with the formula?
A. That's correct.
Q. And then, as you go through the process, after mixing and blending, it's weighed again; correct?
A. Correct.
Q. And --
A. "It," meaning the blend is weighed?
Q. Yes. The blend is weighed again.
And in the validation process, the company should have figured out how much it is supposed to weigh at various steps along the path.
Is that true?
A. I wouldn't state it that way, but I think I understand what you're trying to say. I would say it's true.
Q. And it's -- in essence, it's a quality control check to make sure that you're not losing too much or gaining anything.
Is that right?
A. Well, it's not that you're not losing

or gaining. It's did you put the correct amount of ingredients in?
The issue with that is, if the ingredients are very small, it's kind of like weighing yourself on the Queen Mary.
You know, you jump on the Queen Mary, weigh yourself, then you jump off and you weigh the Queen Mary again, and you subtract to determine that you're X number of pounds.
So yes, it is -- it is a check that is supposed to provide some evidence that the correct ingredients are there, yes.
Q. All right. But let's pick two extreme examples.
If somebody tripped and dumped a bucket of screws into a batch, and there was a weight variance, that would provide a potential check for the company to evaluate why does this batch at the blend stage weigh 5 pounds more than it should; right?
A. I would say it depends.
Q. Okay.
A. It depends on -- do you want me to answer?
Q. I think you've -- I think you gave me

the answer.
A. No. I -- it's a different answer.
MR. MILLER: Matt, why don't you let him -- why don't you let him give the full answer.
MR. MORIARTY: I got the answer I want.
MR. MILLER: You got the answer and you cut him off. Okay.
Q. At the other end of the -- of the spectrum, if accidentally somebody dumped a certain amount of product down the drain, they could check why the batch at a particular stage of the process was too light; correct?
A. They would not necessarily detect it.
As I was going to state earlier, there is a range, an acceptable yield range at every single point in the process.
If those yield ranges are exceeded, then it is out of specification and an investigation would occur.
Q. Okay.
A. If -- if the error occurred so that you threw a screw in there, and it didn't increase the weight of the batch any significant amount, and it stayed within the limits, you'd be oblivious to the fact -- perhaps you would find out in the tableting

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press, but you would be oblivious to it until perhaps a later stage.
Q. Sure. But the purpose of these yield calculations is it's a quality check along the way; right?
A. It is a gross quality check.
Q. There is a lot of weighing and measuring through the whole process; right?
A. It's a gross quality check.
Q. Okay. And do you think that finished product testing, according to the USP methods, is a gross quality check or something else?
A. I -- I wouldn't use the term "gross quality check."
I would say it's a very specific test for tablets. It's a very good test method. And it is likely to detect any products that are out of specification.
Q. All right. And one of the reasons you do all these checks is to see whether a validated process remains in control.
Is that right?
A. One of the reasons you do these things meaning what? "These things"?
Q. You have a formula, you weigh things,

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you measure things, you test them for hardness, all along the route. Is that in order to assure that your validated process remains in control?
A. It is certainly one of the reasons, yes.
Q. Have you ever seen any statement in all the material that you reviewed from FDA to indicate that Digitek manufacturing processes were outside their validated control methods?
A. Yes.
Q. For Digitek?
A. Yeah. I did not look at lot of batches. Yes, with the double-thickness batch. A validated batch cannot produce a double-thick tablet. It is considered invalidated if -- if at end there is the least bit of -- of issue, then you have to assume it is invalidated, is the investigation which goes to the root cause, which then either confirms that it remains a validated state, or, in fact, your investigation determines that there is an issue, and that you don't have a reliable process.
Q. All right. So first of all, before Batch 70924, did you see any evidence from FDA that Digitek manufacturing processes were outside their

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validated control levels?
A. I really have to go back to the 43s and the EIRs to answer that. I'm not trying to avoid the question. I -- I would have to do that.
Q. Okay. In association with Batch 70924, did the FDA ever explicitly say that, "We believe your validated method is out of control"?
MR. MILLER: Object to form.
A. Honestly, I'd have to go back to the records to confirm that.
Q. All right. Well, what I'm trying to find out is, you just gave me your opinion that 70924 indicates an out-of-control process.
I want to make sure that that's your opinion, and not something you saw that the FDA said.
A. I understand.
Did they specifically point to Digitek? I don't recall. I -- I am willing to go back through the records and answer that with, you know, more facts and data.
Q. Okay. You can do that at the lunch break, if you wish.
A. I'd rather have lunch, but okay.
MR. KAPLAN: Well, it is important. I

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just want to say it's very important for us here today to -- to be able to get your opinions and test your opinions. You know you've issued a 35-page report. I think it's fair for us to assume that you've done all the work that you need to do, you've issued your opinions, now we get to ask you about them.
So whatever you need to do to answer our questions, I assume you've done.
But if you need to do something during the lunch break, well, please do it.
MR. MILLER: It doesn't have to be during the break. You can review documents at any point in time.
A. If you -- if you feel it's important enough to get a complete answer on that, I -- I gave my answer. I will gladly go back through it --
MR. KAPLAN: We need the truth, the whole truth and nothing but the truth, and this is our only opportunity to examine you.
THE WITNESS: Sir, I -- I respect that 100 percent. You are getting 100 percent of the truth. You're talking to somebody who does not veer away from the truth. Okay?
MR. MILLER: Yeah, that's -- let's wait

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for a question.
THE WITNESS: Okay. Well --
MR. MILLER: But if you want to review -- if you want to read the documents, then we --
MR. KAPLAN: But when we're told something like, well, I can't answer it because I'd have to do the work all over again, then it's not fair. It's just not fair.
MR. MILLER: He didn't say that. He said, I'll have to review the documents. You can certainly put the documents in front of him.
MR. MORIARTY: Can I get back to work?
THE WITNESS: Yeah. I'm sorry.
MR. MORIARTY: Thanks.
THE WITNESS: Can I take a bio break? I need a very quick bio break.
MR. MILLER: This is a good time for lunch.
MR. MORIARTY: Can you hang on for four minutes?
THE WITNESS: Four minutes. Okay.
Q. If a company -- if a pharmaceutical company consistently put too much active pharmaceutical ingredient into its batches, is it

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more likely than not that their accounting for raw materials in inventory wouldn't reconcile?
A. I can't answer that question. It depends upon the percentage of -- of active that they put in.
Again, when they reconcile, there's an acceptable tolerance. The tolerance is based upon the history.
If the history is such that you add too much, then it would be -- it would be hidden within those specifications.
But, to answer your question again, that is one of the control checks which you have to try to determine whether or not you have misuse -- you use too much or too little.
Q. Okay. If a pharmaceutical company consistently put so much active pharmaceutical ingredient extra into its batches that they were outside the specifications, would that be something likely would be detected by --
A. So you're talking about if they -- if we used hypothetical -- let's say produced a product that was outside of specification which was consistently above 110 percent.
Q. Yep.

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A. Would the --
Q. It's actually 105.
A. 105. The other one said 110.
Q. Trust me.
A. Well, I'm not necessarily going to trust you on this, but -- but it's above -- well, 105 is harder, so I'll use the 105.
Would it be detected in the long run if you --
Q. Likely. Would it likely be detected in the long run.
A. You know what, without looking at their -- without looking at their yield limits, I don't know how I could make that determination.
Q. Would the added Digoxin likely be detected at either blend uniformity or finished product testing?
MR. MILLER: Objection to form.
A. Just repeat that, please.
Q. If the company consistently added such an amount of additional Digoxin that it was going to be outside the specifications, would it likely be detected by blend uniformity or finished product testing?
A. Yes, it would, if they have a valid

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test method.
MR. MORIARTY: Let's stop there because I'm going to push beyond four minutes and I don't want to do that to you. And then do you want to just take our lunch break?
MR. MILLER: Yes.
THE VIDEOGRAPHER: Please stand by. We are going off the record. The time is 12:18 P.M. This is the end of Tape No. 3.
(Lunch recess was taken.)
THE VIDEOGRAPHER: We are back on the record. The time is 1:37 P.M. This is the beginning of Tape No. 4.
Q. All right, Mr. Kenny. Let me do -- first start the afternoon with a little bit of cleanups from some things.
(Exhibit 22, letter dated 1/9/07, was marked for identification.)
Q. And I want to show you what's been marked as Exhibit 22.
This is a letter dated January 9, 2007, from FDA to Actavis; correct?
A. Correct.
Q. It is a warning letter; correct?
A. Correct.

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Q. And if you go to the second to last page, last paragraph, I'd like you to follow along with me.

It says, "While the corrections that you promise in your correspondence appear to adequately address many of the cGMP deviations found during the July 10 through August 10, 2006 inspection, we are concerned about the quality of drug products that have been released from your facility under the serious lack of cGMP controls found during the inspection."

Did I read that correctly so far?

A. I believe so.

Q. And then I'm going to skip the next sentence -- well, actually, let's go on to the next sentence.

"Your response provides no assurance."

Now, "provides no assurance" is a frequent term used in FDA regulatory materials; correct?

A. Um-hum.

Q. That's a yes?

A. Yes.

Q. "That the records and conditions of manufacture and testing of each such lot of drug

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products released and marketed will be evaluated to assure that the released drug products have their appropriate identity, strength, quality, and purity."

Again, "identity, strength, quality, and purity" are regulatory terms frequently contained in FDA materials; correct?

MR. MILLER: Object to form.

A. Yes.

Q. Now, the next sentence says, "We feel that to provide such assurance, your firm should promptly initiate an audit program by a third-party having appropriate cGMP expertise to provide assurance that all marketed lots of drug products that remain within expiration have their appropriate identity, strength, quality and purity."

Did I read that correctly?

A. Yes.

Q. Do you understand this to be the invitation which led Actavis to retain Quantic Regulatory Services?

A. I believe it is the invitation to bring in a consultant, which became Quantic.

Q. And we have already gone over the Quantic exhibit. I don't need to discuss that

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again.

But do you know whether FDA ever expressed any dissatisfaction with Quantic's results such that they did not provide assurances that Digitek had been produced under conditions which assured appropriate identity, strength, quality and purity?

A. Yeah. I think that the FDA had a high level of concern based upon a complete system issue, not necessarily -- taking a look at each of the quality systems.

MR. KAPLAN: I would ask the reporter -- I move to strike that answer as not being responsive.

MR. MORIARTY: And I understand your answer, but one --

MR. KAPLAN: I'd like the reporter to read back the question that you asked so he can answer that question.

MR. MORIARTY: And actually my question was very bad. Your -- your answer wasn't responsive, but my question was pretty bad. Okay?

MR. MILLER: I know --

MR. MORIARTY: Early on -- early on after lunch, it's difficult to keep going.

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Q. What I'm asking specifically is whether FDA ever said, "Sorry, Actavis" or "Sorry, Quantic," the letter you, and results, you provided in December of 2007 don't give us the assurances that we need concerning Digitek.

MR. MILLER: Object to form.

Q. Anything like that in the material you reviewed?

A. I think their actions, the regulatory and escalating of their actions state that they weren't satisfied with their response.

Q. Is there an explicit statement anywhere in the materials you reviewed about Digitek, they were not satisfied with Quantic's work in regard to this specific invitation?

A. I don't recall.

Q. In your Tab 2 -- I'm sorry. Tab -- I'm sorry, Tab 5. Reference 5 in your Appendix B is this definition of adulterated; correct?

A. Correct.

Q. All right. Well, we -- we printed this from the website, and probably have other copies of it, but this is the specific part about strength, quality and purity differing from official compendium; correct?

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A. Um-hum.
Q. Is that a yes?
A. Yes. Sorry, right.
Q. And this is CFR 351B; correct?
A. Correct.
Q. Now, in this paragraph, is that language -- again we're talking about assurances that a product meets identity, purity, strength, etcetera; correct?
A. Correct.
Q. Now, is there anything in here that defines what an assurance is?
A. Can I read it?
I don't see that.
Q. All right. In other words, there's no statement that -- of confidence intervals or statistical probabilities in any precise mathematical terms; correct?
A. Correct.
Q. Are the -- are the general -- are the good manufacturing practice regulations subject to varying interpretations from time to time?
A. By whom?
Q. Well, between a company and the FDA, for example.

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A. I'm sorry. Would you repeat that?
Q. Sure. I mean could two reasonable professionals, even in your field, look at a definition in the GMP guidelines and have a legitimate debate about what a particular word or phrase means?
A. Yes, sir.
Q. All right. So as far as the word "assurance" is concerned, some expert like you could say, I believe that we, as a company, have provided the adequate assurance; and somebody else on the other side could say, no, I disagree; right?
A. That's correct.
Q. And at least the FDA reg itself doesn't provide specific guidance on what that means; right?
A. In terms of assurance, sure it does. It gives you guidance document and it tells you the minimum requirements, and if you perform the minimum requirements, you have assured, to at least a -- to a legal standpoint that you've assured that the product will meet -- will meet all specifications, etcetera, GMP regulations, and will not be an adulterated product.
Q. You mean from a regulatory standpoint.
A. I mean they're linked. Whether --

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whether you're talking about adulterated product meaning total GMP compliance issue, and no spec -- and no out of specifications, that's -- let's say that's stated there. But the assurance that they're implying is, also, that the product going out the door is -- is compliant to specifications. So it refers to, I believe, both.
Q. But the FDA statement in their July -- or their cGMP statement that we went over before doesn't necessarily equate the assurance of regulatory with the actual laboratory outcome of tested product; correct?
A. Seriously, I don't understand the question.
Q. That's fine.
You have expressed opinions in your report that you have -- you believe that Actavis had serious GMP issues in certain years; correct?
A. Through the years I had evidence, yes.
Q. Okay. At the same time, FDA was testing product in 2007/2008, and it was meeting specifications; correct?
A. Correct. It appears, you've shown me a lot of information to suggest that it met specifications.

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Q. Right. And you've not shown me any evidence in the material you reviewed to the contrary, that it didn't meet specifications; correct?
A. Well, we haven't discussed -- you've talked about whether or not a product tests as a final product meets the specifications.
Q. Right.
A. Yes. When you've asked me that question, I've said yes. I don't have any data for that. But I have data prior to that. I mean, there's -- there's tons of things prior to that that would implicate the quality of that particular product.
Q. We'll get to that later.
But in the end --
A. I mean actual test results.
Q. -- if a consumer is going to take a tablet and it meets the USP specs for weight, thickness, content uniformity, assay, all those things, that -- and there's -- and there's testing to indicate that that batch meets those, validated reliable testing, it's generally going to be safe for the consumer; correct?
A. Right. Yes.

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Q. Okay. Thank you.
(Exhibit 37, Recall Package 2009 was marked for identification.)
Q. Exhibit 37, have you ever seen this before?
A. I haven't gone through this.
Q. Does that mean that --
A. Well, it might have been in here. I may -- I may have glanced at it. I don't recall having read it.
Q. All right. This is the FDA approved Recall Package for Digitek in April/May 2008. Okay? Have you seen a Recall Package before?
A. Recall Package before? Not in years, since I didn't have a lot of them.
Q. Okay. At the third page, under "Reason for the recall," does it say Digoxin tablets exceeded tablet thickness specifications?
A. Yes.
Q. Now, have you ever seen a batch record for any other batch of Digitek, besides 70924, in which tablets exceeded thickness specifications?
A. Have I looked at the batch records? No. I've seen some evidence in E-mails and the like that they were overweight, the tablets were

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overweight, double tablets were overweight.
Q. Okay. Well, have you ever seen any evidence, in any other batch record or any other E-mail, or anything else, to indicate that the tablets released to the market exceeded their thickness specifications?
A. Exceeded the thickness? Can I look at my report for one second?
Q. Yes.
A. Could you rephrase your question? You can ask --
MR. KAPLAN: Why don't you have the reporter read it back.
(Requested portion is read.)
A. Thickness? I would have to say I can't recall at the moment.
MR. KAPLAN: Is that a no?
THE WITNESS: That's I cannot recall.
MR. KAPLAN: Yes or no?
THE WITNESS: I cannot -- I cannot recall is my answer, if I'm allowed to give that answer.
MR. MORIARTY: Can I follow up?
Q. I mean, this is a products liability litigation over whether Digitek tablets exceeded

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specifications and harmed consumers. Okay? It's important for me to know whether you, as an expert against my client in this case, have evidence, documents, testimony, and the like, to indicate the tablets that exceeded, and that's what I'm asking you about right now, tablets exceeded thickness specifications got to consumers.
A. Thickness -- can I look at an APR for one second?
Q. A what?
A. An APR.
MR. MILLER: Certainly.
MR. MORIARTY: What's an APR?
A. I'm looking at a number of out-of-specifications for blend uniformity. Let me see.
Q. Remember my question involves tablets that reached consumers.
A. Okay. For thickness, no.
Q. All right. Have you seen -- now, I asked you this before lunch, I asked if you had seen any evidence, or had an opinion to a probability that out-of-spec tablets of normal size, but varying API, reached consumers, and you told me no. Do you have evidence now, after the

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lunch break, that tablets of normal size with varying API reached consumers?
A. Potentially.
Q. You potentially have evidence?
A. Yeah. Because you're talking about probabilities, or possibilities. Would you like me to go through it?
Q. No. You're talking about a blend uniformity issue?
A. Correct.
Q. Did that batch --
A. The batches.
Q. -- test appropriately in finished product testing?
A. They tested appropriately at end product testing. They found it -- can I clarify?
Q. I'm asking one question at a time.
A. Surely. Go ahead. Sorry.
Q. So they tested appropriately in finished product testing; correct?
A. The end product testing sample that was taken was within specification.
Q. Okay.
A. And at the very end of the process.

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Q. All right. And at the blend uniformity stage, and we'll get into the details of this investigation way later, you're talking about one out of the ten samples on the initial run was out of spec; correct?
A. I don't know. The information I received doesn't have that type of specificity.
I'm looking at the APR.
Q. You haven't reviewed the details of the blend uniformity investigations that were done on these batches?
A. No.
Q. Exhibit 37 contains -- has other information in it like the health hazard evaluation.
Is that right?
And then a list of all the batches that might be subject to the recall.
Is that correct?
A. Are we talking about the document I have?
Q. Exhibit 37.
A. Okay. And your question is?
Q. Does it contain a health hazard evaluation and a list of all the batches that might be potentially related to the recall?

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A. Normally it would have it, a health hazard evaluation, and it should list the batches. I'd have to go through it to confirm that, but...
Q. And do you know whether or not the contents of a Recall Package are run past the FDA?
A. I'm not sure, but I -- it probably is.
Certainly I know of instances where it is.
Q. I asked you earlier about Exhibit 39, the July 2009 FDA statement about generic drugs, and specifically the paragraph about Digitek.
Do you remember those questions?
A. I'd like to reread it, but I remember we went over it.
Q. It's 38, Exhibit 38.
That information -- that information, to your knowledge, is still on the FDA's website, isn't it?
A. I have no reason to believe they took it off.
Q. All right. And that would be available not only to consumers, but to medical professionals?
A. The -- the information is available to anyone who has an internet connection.
Q. And that would include consumers and

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medical professionals.
A. They're part of that, yes.
Q. And that would include regulatory and quality professionals in the pharmaceutical industry. Is that correct?
MR. MILLER: Object to the form. It's outside the scope. He's not here as an expert on who's going to have access to the internet.
A. Common sense would tell you everybody has access, and they are part of everybody.
Q. You -- do you have any reason to believe that the FDA is -- has posted anything that it believes is inaccurate in Exhibit 38?
MR. MILLER: Object to form.
A. Please ask that again.
Q. Sure. Would you assume that FDA investigated the facts behind that posting and the content of the posting?
MR. MILLER: Object to form.
A. Honestly, I don't know. I don't know.
I know they would check guidance documents, etcetera. I don't know if they check things like that, so I don't know who would do it.
Q. Did you review or rely on any materials that are not listed in Appendix B to your report?

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A. Did I rely on them? No.
Q. Did you bring anything with you today in your binders, or other materials, that is not listed in exhibit -- I'm sorry -- Appendix B to your report?
A. Yes.
Q. What did you bring with you --
A. I brought everything that I made a copy of.
Q. Do you know --
A. Which is everything that's pertinent to -- to provide me information to try to make some decision or some judgment.
Q. And you believe that there are some things in those materials that aren't listed in Appendix B?
A. Oh, I know there are. I know there are, sir.
Q. All right.
A. That's why I brought them.
MR. MORIARTY: At some point, Pete, we're going to have to go through the binders, identify what's not in B.
MR. MILLER: Okay.
MR. MORIARTY: And I would prefer that

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the court reporter take them, copy them, so that we can have them, and then return what we remove from Mr. Kenny's binders to Mr. Kenny, either directly or through you.

MR. MILLER: Procedurally I have no problem with that. Actually, I'd like to be part of it and take a look at each document before it goes to --

THE WITNESS: And will I be able to get these documents back?

MR. MORIARTY: You will.

THE WITNESS: Within a reasonable period of time?

MR. MORIARTY: You will.

A. Okay. You become attached to documents.

Q. The report that you signed on June 15, 2010, that's your final report; correct?

A. That's the report I submitted, correct.

Q. And were there drafts of this report before this final version?

A. Yes, there were.

Q. Did you bring drafts with you?

A. No. But I can.

The drafts are electronic.

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I did not have an opportunity to go through my files, because they're in multiple places, to give you each iteration of what I did.

But I would go along and occasionally save a copy at a certain period of time, and then continue.

But I can provide that to you.

Q. Okay. Let's get back to where we left off before the lunch break.

I was asking you a series of questions about, you know, what would happen if a manufacturer consistently put too much API in its batches, and would it be detected.

And just before lunch you said, yeah, likely it would, if the company or FDA was using valid test methods.

Do you remember that?

A. Yes.

Q. And in the course of a long day like this, when we're talking about a lot of different documents and topics, sometimes we jump around and sometimes, accidentally, I repeat myself. Okay?

A. Um-hum.

Q. So please excuse me if I do.

But have you seen any FDA citations or

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warnings or observations indicating that Actavis did not have validated test methods for Digitek?

MR. MILLER: Objection. Asked and answered.

It's okay to answer.

A. I would have to look at the records.

And the reason I say that is an out-of-specification result that has not been investigated, you don't know if it's an assay issue, or you don't know if it's a content issue. So without the investigation, I can't tell you whether the root cause of that, which goes back to when the FDA found, as I did, out-of-specification tests, and there is an adequate investigation, you don't know whether it's a valid test method, a valid process, you know nothing.

And then they retest and it looks good, so they pass it.

Q. Did you see instances of out-of-spec results in the materials that were not investigated at all?

A. I saw instances where a root cause determination could not be made, and I saw instances where retesting was conducted, and on Digitek, and without a root cause investigation, retesting of the

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product and releasing it is not an acceptable, compliant procedure, not an acceptable practice.

You cannot test the quality into a product merely by taking a secondary sample.

Q. Do you always find a root cause when you do an investigation?

A. Do you always find a root cause? No.

Q. What is the scientific judgment rule in batch release?

A. Scientific judgment rule? It's not scientific. It's do the numbers meet the specifications. Science is not involved. The people who review it are not scientists. They look, is it filled in, are there results in specification, are there any unexplained cross-outs, and the like, but it is a rather routine review, and it's only is by exception that it gets escalated to somebody with a greater level of technical abilities.

Q. Again, we'll get to blend uniformity failures in more detail later, but did FDA ever make a 483 observation, or a warning letter observation, to the effect that the lack of root cause determinations in blend uniformity investigations should have led to batch rejection?

A. I don't recall, the way you've phrased

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it. I honestly don't recall.
I'd have to go back to the 483s. There are 172 observations, or whatever it is.
Q. Did you see any information in any of this material that the FDA asked Actavis to ever recall Digitek batches before April of 2008?
A. I don't recall seeing anything.
Q. Is there an FDA reg anywhere which specifically indicates that an out-of-spec test result, 1 out of 10, at the blend uniformity stage, mandates batch rejection?
A. There are -- I don't know if it's 1 out of 10. What they specifically state is, if the test results are out of specification, then you have to follow a logical train of -- of investigation and testing that's consistent with GMP.
So I can't tell you whether it is 1 out of 10, or 2 out of 10, or 1 out of a thousand.
Q. All right. But what the reg essentially says is, if you -- if you get an out-of-spec result, you do an investigation; correct?
A. Correct.
Q. It doesn't mandate batch rejection just because you get an out-of-specification result, does

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it?
A. That, in and of itself, would not necessarily -- well, no. The batch would be rejected -- the batch would be placed in quarantine until an adequate investigation could be conducted.
After the investigation takes place, there may be a determination that it's acceptable. Perhaps they have done an investigation that's acceptable to resample and retest, and then the -- in this case -- well, whatever. Did I answer your question?
Q. Yes.
Whether it's at the blend uniformity stage or at finished product testing, would I be correct in saying that there are several different reasons why there could be an out-of-spec?
A. Oh, my gosh. Of course.
Q. Okay. And some of them include sampling errors. Is that right?
A. Yes.
Q. Math errors.
A. Sure.
Q. An out-of-spec test result in the course of this does not necessarily mean a product is, in fact, out of spec; correct?

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A. It has to be assumed that unless you have a root cause, that you cannot discount the fact that a sample tested out of spec. You cannot take a secondary sample, test it, and release a batch.
Q. Where is that in the regulations?
A. I can tell you that it is absolutely 100 percent industry practice, in every company.
If I ever saw a company, and I audited, that went in, found no root cause determination, had initial out-of-specification, decided that they were going to resample, and that it was fine, I would -- I would have to take issue.
MR. KAPLAN: I move to strike the last answer as non-responsive to the question.
Q. So if the root cause was determined to be a math error, and on retest, it was fine, you could release the batch; correct?
A. If you found a root cause, and if you could discount, you could ignore, you could justify the fact and understand the fact that samples were out of specification, and it makes sense to you, then you can, if you will, retest the product using a sample inspection.
But it is very important that you have to get the root cause determined.

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I've never -- I don't think I've ever released a batch, I'm sure I've never, where I had initial out-of-specification, I couldn't figure out why, and decided, for whatever reason, to retest -- it's okay to retest, but I would do it as a diagnostic test, not as an acceptance determination test.
At that point, it would become an experimental batch, as far as I was concerned.
Q. Is blend uniformity sampling considered difficult?
A. No. It should not be difficult.
Q. Do most companies struggle with blend uniformity?
A. The companies I've worked with, content uniformity is not, in general, a major issue.
Q. I was asking about blend uniformity.
A. Blend uniformity. I'm sorry.
No. It's -- I don't find, in the companies that I work with, that blend uniformity is an issue.
Q. Okay.
We touched a little bit before the lunch break about batch yields.
Let's get back to that.

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A. Surely.
Q. There's always going to be some waste, for various reasons, in the pharmaceutical manufacturing process of solid oral dose; correct?
A. Yes.
Q. And if, for whatever reason, a company was consistently making double-thick tablets, the batch theoretic -- or the yield numbers would not match the theoretical numbers; correct?
A. I don't understand what "constantly" means, but if --
Q. I said consistently.
A. Consistently. If they consistently -- I can't answer the question. I mean, I would say that I have to know more about how many units you're talking about, how often. I'd have to take a look at the yield specifications. We'd have to do a mathematical determination. Then, after that, we could, you know, come to -- between the two of us, come to a conclusion that, yes, it could be affected, or no, it's -- it's buried within the tolerances.
Q. Have you done such an analysis for your work here?
A. As part of my work here, no.

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I would need all the -- I would need an unlimited amount of data.
This is something that Digitek is expected to do -- or I'm sorry, Actavis.
Q. Have you ever seen anything in the FDA documents, in your review of this case, to indicate that there were double-thick tablets for any product other than Digitek?
A. No.
MR. KAPLAN: Is there an answer?
MR. MORIARTY: He said no.
THE WITNESS: I didn't say that loudly?
MR. MILLER: It came across to me.
THE WITNESS: I'll try to be louder.
Q. Did you ever see any observations in the 483s or the warning letters in which the FDA asked Actavis to increase its sampling rate for Digitek?
A. I don't recall seeing that, no.
Q. Have you ever actually seen a Digitek tablet?
A. I've seen a picture of it on the internet.
Q. So you haven't --
A. I haven't touched one.

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Q. Okay. You haven't weighed one --
A. No.
Q. -- or anything like that?
A. No.
Q. You know what a Stokes BB2 tablet press is?
A. Relatively, sure.
Q. Does Johnson & Johnson ever use them?
A. I don't believe they use them anymore, but they certainly did years ago.
Q. Do you know when Johnson & Johnson stopped using Stokes BB2 --
A. Well, you're talking about, again, a $60 billion company that has 140 operating units.
If you're talking about the experience that I've had -- actually, I -- the companies I've been with, we did not use Stokes.
Q. Is there any regulation, any FDA regulation that specifies a particular age of equipment, or type of equipment, that has to be used for the manufacture of a solid oral dose product?
A. Age, no. Condition, yes.
Q. Okay. Condition.
Do you know whether or not the Stokes BB2 presses were in use for Digitek at the time of the

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ANDA?
A. At the time of the information that I've read, a Stokes press was being used.
Q. Is the fact that Actavis uses Stokes BB2 tablet presses in all the batch records?
A. Is it -- I don't know. I'd have to look through all the batch records.
Q. Did FDA ever make a 483 observation, or a warning letter observation, to the effect that Actavis should not be using Stokes BB2 tablet presses to manufacture Digitek?
A. I don't recall that that -- that suggestion was made.
Q. Are you an expert in manu -- tablet manufacturing equipment with weight controls?
A. No, I'm not.
Q. Are you aware, from your review in this litigation, that when UDL had Digitek tablets, it performed random weight and thickness tests to make sure that the tablets would fit into their blister packs?
A. I saw testing being conducted. I don't know how often, but I saw test results.
Q. Do you know whether UDL ever found Digitek tablets that were outside the USP thickness

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or weight specifications?
A. I would have no way of knowing that.
I would have -- I would have to see all the results.
If I saw the results, then I could say -- in random, then I'd say yeah, they're all in spec.
Q. Well, when the Plaintiffs' lawyers deposed the UDL employees, and had the UDL documents, was there anything that came out in those depositions, or those exhibits, to indicate that UDL ever found tablets outside the USP weight or thickness specifications?
A. I don't recall any instances.
Q. We touched on adverse event reporting a little bit this morning.
How much do you know about the FDA's adverse event reporting database?
A. Not a lot.
Q. All right. Are you aware that the FDA generally considers that that system does not reflect causation?
MR. MILLER: Object to form.
A. I'm not familiar enough and I couldn't hazard a guess.

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Q. All right. Okay. Would you prefer to rely on pharmacovigilance experts to discuss issues like that in this litigation?
A. Would I rely upon them?
I don't know who the experts are. You know, I can't say I would or wouldn't.
I mean, people who say they're experts are not necessarily experts.
Q. That's true.
You're not professing expertise in pharmacovigilance, are you?
A. I have never professed that.
Q. Have you ever seen any data which compares adverse event experience for Digitek with that of any of its competitors?
A. Could you repeat that?
Q. Sure.
A. The statement "competitors."
Q. Have you ever seen any data that compares adverse events experience for Digitek with adverse event experience for any other Digoxin product?
A. I don't recall. It would not be something that I would have focused on because it's outside of my expertise. I don't know what I would

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do with the information.
Q. Have you read the depositions of any doctors --
A. No.
Q. -- who have been taken in this case?
A. No. I have no interest.
Q. Do you know from any independent research whether any hospital reported an increased incidence of Digoxin toxicity in the years 2005, '06, '07 or '08?
A. I did no investigation of any sort, so the answer is I know of nothing, because I didn't do anything.
Does that make sense?
Q. All right. Let me get back to some statistics that I was asking you about before.
Of this 688.2 million tablets that were part of the recall, do you have any opinion, to a reasonable probability, as to what percentage of them were outside the USP specifications on the low side?
A. On the low side?
I have no way of knowing that.
Q. Do you have any opinion, to a probability, of what percentage of those tablets

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were out of spec -- out of the USP specifications on the high side?
A. The -- the -- I'm sorry. Just repeat the question so I can answer it correctly.
Q. Sure.
Do you have an opinion, to a reasonable degree of probability, as to how many of the recalled Digitek tablets were outside the USP specifications on the high side of their active pharmaceutical --
A. I would have no way of knowing that.
Q. Are you an expert in pharmaceutical distribution?
A. No. No.
Q. And when I say distribution, just so we're clear, I mean you work for J&J, which actually makes pharmaceuticals and devices; correct?
A. I did work for them, yes.
Q. And then at some point, they might sell or transfer the product to distributors who get it ultimately on consumer shelves; correct?
A. Yes. I have some knowledge of it. I'm not an expert on it.
Q. All right. That's what I want to find out, is whether you have any expertise on the

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distribution end of this, as opposed to quality and manufacturing.
A. No. I've -- I've audited distribution centers, but I haven't done it -- I look for GMP issues.
Q. Just to make sure I'm clear, you would have no opinion, to a probability, as to any specific Digitek batch, as to how many of those tablets were outside their USP specifications; correct?
A. Well, you say "any." There is a lot of information on Batch 70924, so I -- I would have an opinion on whether or not additional tablets were -- of double thickness or were thick that went out. So I would have an opinion on that.
Q. Okay. Other than that.
A. Other than that --
Q. If I went through the list of 152 batches that actually made it to market, that had to come back, you would have no opinion to a probability as to any of them other than 70924?
A. No. No. I would have to say, no, that's not correct.
When I evaluate a company, I evaluate it for all those control systems and procedures that

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can affect the quality of the outgoing product.
When I see a company that has most of their systems out of control, if you will, or not within control, or examples where they're not within control, I have a high level of concern that the product they are releasing is not conforming to specification. I know it -- I know it's adulterated because of all the GMP issues. The question is, does it meet specification.
I would have a very high level of concern with that. I would have -- and I don't know, does that help answer my question -- or your question?
Q. Are you done with your answer?
A. I think so.
Q. Okay. Well, I don't mean to repeat myself, but I need to make sure I understand this.
Based on your review, you have a high concern about this, whether product met specifications; correct?
A. I have a very high concern about it.
Q. Okay. But if -- but if I understand it, you've never seen reports of double-thick tablets in the hands of consumers, or pharmacists, from recall batches. You've never seen lab tests

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of --
A. Of what?
Q. -- of out-of-spec tablets; correct?
A. Lab tests of out-of-spec tablets in the field?
Q. Yes.
A. Okay. Well, there are plenty of tests that are unreleased batches.
Q. But --
A. It's --
Q. -- unreleased batches aren't in the hands of consumers, are they?
A. That's not -- that's correct.
Q. Okay.
A. But they are a high level of concern because they implicate the quality of those that have been released.
Q. Well, isn't the purpose of the Quality Department to reject batches that are out of spec for some reason?
A. The primary objective of the Quality Assurance Department is to make sure that controls and systems are in place. That's the primary responsibility.
A secondary responsibility, as a safety

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net, is to take samples at the end of the process and test them.
But the primary -- it's a very, very small part of what Quality Assurance and Quality Control does.
Q. If a company finds a batch that's out of spec, truly out of spec, it should be rejected; correct?
A. If they find a batch that's truly -- well, of course.
Q. So Batch 8022 --
A. The "truly" part is --
Q. Well, 80228, which, from your review, had tablets that were out of spec by weight was rejected; correct?
A. Was rejected? No. Not all of them were rejected.
Q. Do you think 80228 went to market?
A. I'd have to -- I'd have to look at the record. May I?
Q. Sure.
A. I don't know if they went out to market. In the records I looked at, I don't know if they were released.
I'd love to have seen 2008 APRs because

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then it could confirm to me whether or not they were released.
MR. KAPLAN: I'm going move to strike the last answer. It's not responsive.
THE WITNESS: It's what?
MR. KAPLAN: Not responsive to the question that was asked. It is a gratuitous statement.
Q. All right. Let me just -- I -- I believe I've asked this, and I don't mean to ask it over and over again.
I thought I heard you say on several occasions today that you have no evidence in the material you have reviewed of out-of-spec Digitek tablets actually in the hands of consumers.
MR. MILLER: Objection.
Q. Am I correct about that?
MR. MILLER: Objection. Misstates the previous testimony.
Q. Then I guess I have to keep asking.
A. Could you ask it again?
Q. Because if it did --
A. Could you ask it one more time?
Q. Mr. Kenny --
A. Could you rephrase it?

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Q. I'll get there. Okay? I want to make it clear to you.
I understand that you have GMP concerns about my client and you have concerns about whether Digitek was within or without the specifications; correct?
A. Correct.
Q. And I've shown you all kinds of 484s where the FDA tested the product; correct?
A. That's correct.
Q. And documents with Celsis labs tested the product and it all met the specs; correct?
A. Of what the -- evidence I've seen, correct.
Q. Done by sampling plans chosen by Celsis and the FDA pursuant to the U.S.; correct?
A. Well, it was a sampling plan of just taking a few units. It was done by a sampling plan.
Q. Done by the U.S. -- according to USP methods; correct?
A. Yes.
Q. And FDA regards the USP as essentially the bible, so far as the chemical testing of product; correct?
A. You can use the term "bible." They

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certainly consider it a knowledgeable and valid source of testing.
Q. All right. And you know that the 152 recalled Digitek batches all had quality control testing on them for finished product; correct?
A. I will assume that they did.
Q. And will you assume that they used the USP validated method that the FDA was aware of?
A. The method that they -- no. What I -- what I can assume -- I don't want to assume anything, but for the sake of this -- this conversation, or this discussion, the methodology that they have in their test method is probably the USP method.
Now, did they adequately train the person to perform that analysis? Did they adequately do verification batches to basically validate that the method is acceptable, when tested in their hands, I have seen no evidence to suggest that they've done that.
Q. Well, you've seen no evidence from FDA that indicates they didn't; correct?
A. For -- for what?
Q. The Digitek testing.
A. If you -- okay. You're talking about a

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population here of all products.
Q. No. I'm talking about Digitek.
A. I understand that.
MR. MILLER: But let the man answer. You are, but I object to the form. You're interrupting him.
A. It -- it's sort of like a Venn diagram. Here's the population. If you say that they're using practices that are out of compliance, the assumption will be since Digitek -- Digitek is part of that large diagram, that they also suffer in many of the issues that are suffered across the plant.
Q. I asked you hours ago whether you ever saw a specific finding from the FDA that Digitek was adulterated, and you said no.
MR. KAPLAN: Object to form.
MR. MILLER: Object to form. Misstates previous testimony.
MR. MORIARTY: I don't think it does, but...
Q. Find for me in the documents a specific statement by the FDA that Digitek was adulterated. Find one, please.
A. Why would -- why would a company --
Q. Find one, please.

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We've already gone over the recall notice.
MR. MILLER: Objection.
Q. We've gone over the Recall Package. You can't ask me why the company would do that because I get to ask the questions. That's my prerogative today.
What I want you to do is show me somewhere in the material you reviewed FDA finding that this product, Digitek, that this litigation is about, was adulterated.
MR. MILLER: Objection. Asked and answered.
THE WITNESS: I beg your pardon?
MR. MILLER: That's okay. Answer it.
A. I don't recall where Digitek -- Digitek was, let's say, clearly stated.
Q. Okay.
A. Does that answer your question?
Q. Yes.
Now, if you had a client in your consulting business and you wanted to know whether GMP issues with -- overall were impacting on a specific product, would you look at batch records for that specific product?

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A. That would be a portion of my investigation.
Q. And do you think FDA would do that?
A. I would assume. I -- I would expect them to take a look at batch records.
If the batch records are not necessarily accurate representations of what happened.
Q. You have no evidence in this case that Actavis --
A. No.
Q. -- has Digitek batch records that are inaccurate in any respect, do you?
A. That's correct.
Q. Now, let's talk about Batch 70924.
A. Okay.
Q. In your opinion, to a probability, were there more double-thick tablets in 70924 than the 20 they found during the investigation?
A. I believe. With a high level of certainty, that, yes, there were.
Q. How many?
A. I have no clue. I just know there were more.
Q. How do you have a high level of

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certainty about that?
A. Because visual inspection is regarded as, and it's in my experience, and as an industry acceptance, that visual inspection is horrendously unreliable to the point that it cannot be relied on.
Q. Is that any kind of visual inspection?
A. No. No. It could be -- I'm talking about human inspection.
At best it's a safety net.
Q. So you have a high degree of certainty there were more, but you don't know how many more; correct?
A. Correct.
Q. Certainly couldn't have been 4 million more; right?
A. I would think it would not be 4 million more.
Q. And you've never seen a report from any consumer that they got a double-thick tablet in 2008; correct?
A. Correct.
Q. 70924 wasn't shipped to market until 2008; right?
A. I don't know.
Q. Have you seen a report from any of the

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litigants in this case, any of the Plaintiffs that they had an actual double-thick tablet?
A. No. I don't know who the litigants are, but I haven't seen that.
Q. Have you seen any report from a pharmacist that there was a double-thick tablet found in 2008?
A. 2008? No.
Q. Do you think that with all these Plaintiffs' lawyers scouring the country for double-thick tablets, they might have found one if there was one?
MR. MILLER: Object to form.
A. I can't -- I can't speak to that. I don't know what they did.
Q. In the material that you reviewed to prepare opinions was Reference 54 in Appendix B.
It's an article called, "Stop Depending on Inspection."
Do you remember that?
A. Yes, sir.
Q. Is the journal from which this comes -- it's called "Quality Process."
Do you subscribe to that journal?
A. I currently do not. I have for years.

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Q. Does Quality Process --
A. Progress.
Q. -- Progress, I'm sorry, apply to a number of different manufacturing fields?
A. Yes, it does.
Q. Not just pharmaceuticals?
A. Yes, it does.
Q. Is this a peer-reviewed publication?
A. Is it peer-reviewed? I don't know.
Q. Do you know the author of this article?
A. No, I do not know the author.
Q. Well, here at page 40 in this article, it says, "Because 100 percent inspection is only 80 percent accurate, even companies that do 100 percent inspection will allow one out of five defects to slip through."
Do you see that in your -- this article?
A. Yes. That's basically from Juran.
Q. What's Juran? J-U-R-A-N?
A. J-U-R-A-N. He invented -- basically formulated the current, or at least were the pioneers of the current quality practices, and in Juran's book, he comes up with the 80/20, basically stating that a 100 percent inspection is not

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100 percent effective.
Q. Was there a --
A. And he claims -- he claims that there have been studies done that have corroborated that over and over.
As a matter of fact, he gives an example where every time, or frequently, he would go to a conference, or whatever, and he'd ask a certain question, and they would respond to -- it looks like you may have it.
And, apparently, he sees a high -- high number of people who get that wrong, and -- but it is one of the most consistent, generally-accepted numbers that I'm aware of.
Q. Were the studies Juran replied on -- or relied on published?
A. Were they published? I'm sure they were, because he -- he references -- I don't know, is really the correct answer.
He reference -- references a study, but I don't know if the reference is correct. But he is a rather reputable gentleman, or was.
Q. Well, is it going to be your opinion that the 100 percent inspection of Batch 70924 was allowed 20 percent of the tablets through as

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defective?
A. I -- I would not claim that.
Q. Okay.
A. What I would say is that it would not be 100 percent effective.
The issue is that the methodology was not validated, it was not qualified. There was no way of them knowing what level of detection is possible based upon the operators, the methodology, the through-put, without an understanding of how reliable the inspection method is --
Q. Is that -- go ahead.
A. Without an understanding of the inspection method, you basically are dealing in an unknown area.
So you -- you would make the assumption that it is an invalid inspection.
It could have more than 20 percent. It could have less. There's no way of knowing.
Q. And even assuming there were double-thick tablets in 70924, that somehow evaded the 100 percent inspection, do you think they also evaded the tightened AQL inspection that followed?
A. The tightened AQL inspection is not -- it's not much of a -- a challenge.

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It tested 1250 tablets out of 4.7 million.
The probability that they would detect levels of -- of 1, 2 is very low.
Q. And --
A. In fact -- go ahead.
Q. Go ahead.
A. I said, in fact, the sampling method they used would allow -- would accept on one reject, which is an incredible, I would say, violation of the whole quality assurance practice.
Q. You'd certainly agree that Batch 70924 A got more inspections than any other batch that you're aware of.
A. I think it did. I'd say more inspections.
Q. Yes.
A. It got -- it got 100 percent inspections, purportedly.
Q. So even if there were some unknown number of double-thick tablets that made it into containers and went to Mylan, and then downstream to consumers, you don't know how many of them were in any given drugstore; correct?
A. Correct.

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Q. In any given container that a consumer received; correct?
A. Correct.
Q. Whether they went to California, or Oregon, or Florida, or anywhere else; correct?
A. I have no idea where they went.
Q. Wasn't the tightened AQL developed under the highest level of scrutiny under the mill standard 105 that you referred to earlier.
A. The -- it was --
Q. First of all, yes or no?
A. Well, the way you phrased it, no.
Q. Okay. What do you disagree with about that question?
A. Could you repeat the question?
Q. Was the heightened AQL inspection that was done on Digitek Batch 70924 done under mill standard 105?
A. That's not what you asked.
Q. Okay. I'm asking you a new question.
A. Oh, the new question. I got it.
MR. MILLER: He asked you to repeat the question. He was assuming that's what you were doing. So now it's a new question.
Q. I'm sorry. Go on.

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A. So you're asking what -- sorry. Now you have to repeat it.
Q. Was the 70924 heightened AQL inspection done according to mill standard 105?
A. I believe it was, yes. I looked at the numbers and it looks correct.
Q. Was that the highest level of scrutiny under mill standard 105?
A. I don't recall, but I don't believe so. I'd have to go through 105, but I don't believe that's the -- highest standard meaning the highest level of scrutiny, no. I don't think so, but I'm not sure.
Q. Certainly 100 percent is a higher level of scrutiny than a heightened AQL of that nature; correct?
A. Not necessarily, no.
Q. Now, I asked you a little bit ago whether you had an opinion to a probability as to numbers of tablets that were below or in excess of the USP's API specs.
Do you remember those questions?
A. Sure.
Q. And you said you had no opinion as to a probability as to whether those numbers were high or low; correct?

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A. Could you repeat it again? I want to make sure that I'm answering the question.
MR. MORIARTY: Read my question back, please.
(Requested portion is read back.)
MR. MILLER: I object to the form.
A. I'm not --
MR. MILLER: I'm not so sure I understand what you're asking.
Q. Let me get to my numbers.
All right. Out of 152 recalled batches, if you do the math, it's roughly 688 of a million tablets. Okay?
A. I recall, yes.
Q. I asked you whether you had an opinion to a probability as to what percentage of those were outside the USP specs high, and you said you had no such opinion to a probability.
Am I correct on that?
A. Of the number. You asked me if I have a probability of a certain number.
I have no idea what the number could have been.
Q. Okay. And I asked the same question as to low, and you had the same opinion; correct?

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A. Yeah. I have no way of knowing how many were low.
Q. Now, even assuming, if there were some that were outside the specs high --
A. Um-hum.
Q. -- you would have no opinion to a reasonable probability as to how high.
Is that right?
A. Well, I know --
MR. MILLER: Objection.
A. I know there's some double thickness, but -- I'm not sure I can answer the question without hearing it again. I'm sorry. I must be getting tired.
Maybe this is an a good time for a break.
Q. Let's finish this, and then we can take a break.
Even if there were some number of Digitek tablets among the recalled batches that were outside the USP specs high --
A. Right.
Q. -- do you have an opinion, to a reasonable degree of probability, as to how far outside the specs high they were?

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MR. MILLER: Object to form.
You can answer.
A. I have no way of knowing.
Q. All right. Same thing on the low side.
A. I have no way of knowing.
Q. Okay.
MR. MORIARTY: All right. If you want to take a break, let's take one now.
THE VIDEOGRAPHER: Stand by. We are going off the record. The time is 2:52 P.M. This is the end of Tape No. 4.
(Recess was taken.)
THE VIDEOGRAPHER: We are back on the record. The time is 3:02 P.M. This is the beginning of Tape No. 5.
Q. Have you ever -- Mr. Kenny, have you ever seen any evidence in the material that you reviewed that Digitek was ever cross-contaminated with another product made at Actavis during this time?
A. I saw that cleaning validation wasn't adequate, but I didn't see a product that was cross-contaminated.
Q. Technically speaking, it was not the cleaning validation that was inadequate, it was

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cleaning validation studies that they found inadequate; correct?
A. Well, that's -- cleaning validation is -- cleaning validation, you automatically add the studies on the end.
Q. Well, what the FDA was concerned with was not the cleaning itself, but how you tested whether the cleaning was adequate; correct?
A. Yes. But that's cleaning validation.
Q. I just want to be technically correct.
A. And recovery.
Q. Okay. But you never saw any evidence in anything that there was cross-contamination at any point, did you?
A. I saw no evidence.
(Exhibit 21, Amide Investigation Final Report, was marked for identification.)
Q. Now, in the materials you reviewed, and commented on in your report, was Plaintiff's Exhibit 128, which my team also marked as Defendant's Exhibit 21.
That's the double-thick tablet investigation from 2004; correct?
A. Correct.
Q. And are you aware that the tablet at

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issue was actually made in a batch in 2003?
A. Yes.
Q. And there was only one. Is that correct?
A. Only one what?
Q. Tablet.
A. There's only -- I believe that's correct.
Q. And it was found by a pharmacist. Is that right?
A. I believe that's correct.
Q. Now, I asked you before about the math of this, but if the recall Digitek from mid-2006 forward was 688 million tablets, if we did the math from 2003 forward, the number of Digitek tablets made and distributed would be in the billions; correct?
A. If you say so.
I have no way of knowing those numbers, but there's probably a lot of them.
(Exhibit 20, Summary of Findings, was marked for identification.)
Q. I want to hand you what's been marked as Exhibit 20.
Have you seen this document before?

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A. This was just submitted to me. I have not had a chance to review it.
Q. This is a 2004 EIR, is it not?
A. It appears to be. It says "EI," which tends to mean inspection report.
Q. There are three things I want to ask you about in this document.
So first I'd like you to go to page 4.
Let me ask you a preliminary question.
In order to be under consent decree, do you have to be in compliance with GMPs?
A. In order -- you have to repeat that.
Q. In order to stay under consent decree, do you have to be in compliance with GMPs?
A. Yes.
Q. Now, go to page 4, the first paragraph under "History Of Business Operations," the fourth line down, it says -- it's referring to a consent decree that was in effect from '92 to 2001.
It says, "The consent decree was lifted in 2001 following successful demonstration of sustained cGMP compliance."
Do you see that?
A. Yes.

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Q. And these EIRs, these are FDA documents.
Is that right?
A. Correct.
Q. Now I'd like you to go to page 6. In the paragraph about field alert reporting, the -- first of all, are you aware that Actavis notified the FDA of this 2004 double-thick tablet episode, they notified the FDA through a field alert.
Is that right?
A. That is correct.
Q. And towards the bottom of the paragraph I'm referring to, down here, it says, "No additional complaints or reports of thick tablets have been reviewed for this high-volume product."
Do you see that?
A. Yes, I see that.
Q. "The event was considered an isolated incident, and corrective actions were put in place to prevent its reoccurrence."
Do you see that?
A. Yes.
Q. Do you have any reason to disagree with the FDA about the statement it made in its EIR at that point in time?

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A. Yes.
Q. And what's the basis for your disagreement with the FDA?
A. Because their investigation, in my opinion, based upon my experience, was not adequate. It did not --
Q. In 2004?
A. In 2004.
In other words, there -- a complaint is being handled.
At that particular point, a very thorough investigation would have been expected, which I did not see.
Q. Did FDA criticize, observe or warn --
A. I don't recall.
Q. -- Actavis about its investigation?
A. I don't recall.
Q. Well, don't you think they would have said so in this EIR, had they been concerned about it?
MR. MILLER: Objection to form.
A. I can't tell you what the FDA would have said.
Q. Okay. Let's go to page 9.
Under "Complaints," the second

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paragraph.
It says, "A larger number of complaints was also noted for Digoxin tablets; however, it is the highest volume product, 179 batches manufactured in 2003/2004, according to the list of batches produced per year. There were also no trends observed for the types of complaints."
Do you have any reason to disagree with the FDA about those comments?
A. I have no reason to disagree.
Q. Do you have any criticism of FDA's investigation of the field alert that Actavis filed with them in 2004 about this tablet incident?
A. I have no opinion on it.
Q. And are you -- you're aware, are you not, that tablets made in 2003 would not have been included in the recall in 2008?
A. Yeah. They would not have. I'm assuming they would not have been within expiration, so they would not have been included.
Q. Now, I told you earlier that I was going to make sure that we had -- we knew all the material you brought with you today, and things of that nature.
Okay?

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These are some documents from your file.
I don't know if they were actually pulled from binders.
First of all, did you have exchanges of E-mail with the Plaintiffs' lawyers in this case?
A. There's been some correspondence, yes.
Q. Who's been your primary contact with the Plaintiff's lawyers?
A. I would say Meghan, primarily.
Q. Have you had contact, other than today and maybe yesterday, with Mr. Miller or his firm?
A. Oh, sure. He was always carbon-copied, or most of the time.
Q. But there's been exchange of E-mail?
A. Yes.
Q. Have you printed all the E-mails?
A. I did print them. I don't have them with me.
Q. All right.
A. What I tried to do, just for the record, is I tried to take the E-mail that had the long list, as opposed to -- that covered each of the replies, as opposed to, you know, taking each one individually.

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Q. All right.
A. You may find it in there. I didn't find it this morning when I went through it.
Q. So this particular document is something about Juran's Quality Control Handbook. Is that right? About the 80/20 rule?
A. Yeah. I tried to quote what was in his -- his documentation -- his book, which I have. I've had the book for 20-plus years.
Q. And here you have Plaintiff's Exhibit 133?
A. Yep.
Q. And it has handwriting on it?
A. Yes, it does.
Q. Is that your handwriting?
A. Yes, it is.
Q. And this has to do -- 133 has to do with Quantic's -- Quantic Regulatory Services' investigation, doesn't it?
A. It's hard to tell what it has to do with because it's all blank.
Q. Well, let me make this easy for you.
In your own handwriting, in the middle of the page, doesn't it say "Quantic" with the arrow towards the people on the E-mail?

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A. Yes. Actually Sal Romano wrote that. He told me that that is Quantic. I would have no way of knowing that because I didn't know who it was.
Which is meaningless to me other than the fact that they are a consulting firm.
Q. Now this document does not have a --
A. Right.
Q. -- exhibit sticker on it, and the Mylan Bates number is kind of copied off of the document, but it's a report of December 4, 2006 about an audit.
A. Yes.
Q. Is that right?
A. Yeah. You're not really showing it to me, but I believe it is.
Yeah. I know that document.
Q. This document that I'm holding looks to be the consent decree from 1992; right?
A. Yes.
Q. This document I'm holding is not Bates stamped, and it has no exhibit sticker.
Would you agree with that?
A. Yes.
Q. It is a November 6, 2006 letter to FDA

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on Actavis letterhead, is it not?
A. Yes, it is.
One second. One second.
Q. You can hold it.
A. Okay. Right. Okay.
Q. When did -- is it Mr. Romano or Dr. Romano?
A. Dr. Romano.
Q. When did Dr. Romano cease working on this Digitek matter?
A. Probably around a month ago.
Q. The next document in the stack that I'm holding looks like Exhibit 69 from the Galia deposition.
Is that right?
A. Yes.
Q. This is a -- this is deposition Exhibit 159.
Is that right?
A. Yes.
Q. "Blend failure investigation"?
A. Right.
Q. Now, it has Russ's name above the top redactions. And Sal's name.
What's that all about?

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A. Let me look at it.
Q. First of all, there's handwriting all over it. Is that right?
A. Right. Yes.
Q. Okay. Why are Russ and Sal's names above that --
A. Because I -- I don't want to touch this because I know nothing about technical sampling. I looked at it, and I tried to read it, and I tried to understand. It was foreign to me. I didn't understand the -- some of the terminology. I attempted to, and I said, this is something for either Russ, or if Sal knows something about it, perhaps he can add some insight, which -- which he did not.
Q. All right. Well, this has to do with blend failure investigation, and there are at least two Digitek batches named in this investigation.
Is that right?
A. I'd have to see it, but I'm sure you're right.
Correct. Yes.
Q. So if I understand this correctly, you at least looked at this document.
A. Correct.

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Q. Is that right?
But then because you did not consider yourself to be expert in what they're talking about --
A. The sampling technique, correct.
Q. -- you had Russ and Sal look at it; correct?
A. No. I put a note that Russ and Sal should look at this.
Q. And do you know if they did?
A. I -- I -- since I never communicated with Russ, I assume if he did, it was by his own volition.
Sal, I believe, did take a look at it, and he couldn't add my more depth than I could.
I had difficulty following it.
Q. Is that because this blend uniformity sampling and investigation material that's discussed in here is really quality control chemistry issues?
A. I don't know what the issues are. I can tell you that I don't understand the methodology that's used in order to obtain a representative sample. They were using terms I'm not familiar with.
Q. Are you -- have you ever been a quality

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control chemist?
A. No. I explained that earlier.
Q. Okay. The next document I'm holding is an article called "Drugs with narrow therapeutic index as indicators in the risk management of hospitalized patients."
A. Yes.
Q. Did you read this article?
A. I tried to read it.
Q. This is --
A. Then I realized it was -- quite honestly, I had no familiarity with the term, so I went onto the internet to at least see what the term meant, and then I realized when I went into it -- I tried reading it, just to familiarize myself, but it was clearly out of my territory.
Q. All right. And attached to it is deposition Exhibit 164, 165, and 166.
Is that right?
A. Yes.
Q. Okay. The last document I'm holding here appears to be a draft, "for discussion purposes only," version of your report.
Is that right?
A. Correct.

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Q. To whom did you send this draft?
A. I sent it to Meghan, Sal and Pete.
Q. Was this a first draft?
A. That was a first draft. The first draft that they saw, right.
Q. And then in here, there's handwriting. Is it your handwriting?
A. All of it's mine.
Q. Is the handwriting based on discussions you had with Plaintiffs' counsel about the draft?
A. It is based upon two things, or three, if you will.
One, listening to them.
Secondly, coming up with ideas as I'm just going through the document.
And then later, going back and looking at and making additional edits as I reread it.
Q. Are you left-handed?
A. Yes, I am.
Q. Did you go to Catholic school?
A. High school.
Q. Backwards checkmarks, telltale sign. Takes one to know one.
MR. MORIARTY: Do you want me to mark these as one exhibit? How do you want to take this

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up, because at some point, I need to have more time to go through them, and see if I have questions about them.
MR. MILLER: I'd like to mark them as individual exhibits, but something like the article with the three exhibits attached to it can stay as one exhibit. I mean, we don't need to break it up. But things that are together should stay together, and those that are apart should stay apart.
MR. MORIARTY: What I'd like to do is give these all to the court reporter --
MS. CARTER: Are you talking about those specific handfuls? Aren't we going to make copies of the whole thing?
MR. MORIARTY: Well, we'll get there in a minute. These is what I'm talking about right now. I'll give them to the court reporter.
I will confer with the people in my office as to where we are in exhibits, and then give her the numbers so she can mark them.
MR. ANDERTON: We are at the 91. We've -- and we've already used 100.
MR. MORIARTY: Well, that's where we were yesterday. Is that okay?
MR. MILLER: Okay.

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MR. MORIARTY: We still have to go through these to see if there are things that were not in Appendix B, but I don't need to mark everything he brought.
MR. MILLER: I'm fine with reading the title of what he brought that's not in Appendix B into the record, if that works for you.
MS. CARTER: I didn't know if you wanted to or not.
Q. Are you going to be able to readily identify what is in these binders that is not in Exhibit B?
A. No. I'm -- not readily. Sorry.
Q. So you don't have the E-mails with you today.
Do you have all the attachments to the E-mails here today?
A. Attachments to E-mails.
I don't know if there were any attachments to E-mails.
Like the instructions of -- you know, legal instructions in deposition.
I don't -- I can't, off the top of my head, recall any electronics exchanged other than late copy of the -- on June 15, I think it was, of

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the draft, or thereabouts.
Q. All right. Well, at some point I need you to print -- I need you to get us the E-mails. I need you to print the drafts.
MR. ANDERTON: No. I want them electronically.
THE WITNESS: Okay.
MR. MORIARTY: He wants them electronically.
THE WITNESS: So how should I do that?
MR. MORIARTY: Put them on a thumb drive.
THE WITNESS: No, I mean how to copy it.
MR. ANDERTON: Just transfer them onto some sort of portable drive, thumb drive, disk.
A. I'm not trying to be overly technical. But how do you take an E-mail and copy it? You don't even know where the file is located.
MR. MILLER: I'd have to go with him on that. If told me to put an E-mail on a thumb drive, I'd have no clue how to do it.
MR. MORIARTY: If you -- if you keep -- if you keep an -- if you keep an electronic Digitek file and you keep the E-mails in the file, they

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should be there.
MR. MILLER: I think the notice asked for a hard copy. I think -- I think it satisfies your request if he prints them out and provides you with a hard copy. He's not going to provide you with an electronic copy.
MR. ANDERTON: The note does not ask for just a hard copy -- or the notice does not ask for just a hard copy.
I will accept hard copies of the E-mails, subject to your preserving and not destroying any of the electronic copies.
THE WITNESS: Certainly.
MR. ANDERTON: And with respect to non-E-mails, other drafts I believe you testified about earlier, that you maintain you still have in electronic format --
THE WITNESS: Yes.
MR. ANDERTON: -- I want those electronically.
Anything except an E-mail that relates to this case that you maintain electronically and it isn't part of the binders here, other drafts in particular, you're going to need to transfer onto some sort of portable media.

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THE WITNESS: That's easy.
MR. ANDERTON: Okay. Fair enough. And can -- and there's to be no dealing -- no modifying it electronically. Transfer it, hand them the media --
MR. MILLER: They will be PDFs, they're not going to be Microsoft Words.
MR. ANDERTON: No. I don't want PDFs. I want them --
MR. MILLER: You're going to get PDFs. Yeah, I mean, you know, if you're going to take a software and dissect this thing until he gets to the first letter he typed in, I know that kind of stuff is out there. He's going to give you a PDF, and that's what you're going to get.
MR. ANDERTON: That's not acceptable to me.
MR. MILLER: We will --
MR. MORIARTY: Wait. I don't want to take up my deposition time. Preserve everything you've got in your computer on Digitek, and we'll take this up later.
THE WITNESS: Okay.
MR. MORIARTY: We're not going to agree on this on my record.

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Q. Do you have any knowledge of which consumers, or which Plaintiffs in the Digitek litigation, received which batches of Digitek?
A. Which consumers received what batches.
MR. MILLER: Object to form.
A. I'm not sure I understand the question. You mean from the distribution center?
Q. From anywhere. I mean, Batch 70924 went to market; correct?
A. Yes.
Q. And presumably it was disseminated to pharmacies, and some of it, potentially, to consumers.
Is that correct?
A. Yeah.
Q. Right?
A. Yes. Yes. I'm sorry.
Q. First of all, do you even know for a fact whether any consumers got tablets from 70924 before the recall?
A. I have no way of knowing that.
Q. Okay. So if I went to other batches in the recall and mentioned them by number, would you have any way to know which consumers got tablets from those batches?

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A. No. I don't have any way of knowing.
Q. Do you know anything about how the die -- die table set for Stokes BB2 tablet presses is adjusted?
A. No. That's not my expertise.
Q. Do you have any idea what percent of pharmaceutical manufacturers have tablet presses with weight controls?
A. I have no way of knowing that.
Q. Have you reviewed any manufacturing documents from Actavis Elizabeth?
A. I don't believe so. No, I don't think so. I don't recall any.
Q. How many of the 483s between 2006 and 2008, January 2006 to April of 2008, specifically refer to Digitek?
A. Specifically refer to Digitek. I would say there's -- I'd have to look through them, if you'd allow me. But I think there's --
Q. How many?
A. -- specifically, one. That's -- I don't -- I'd have to look at them, honestly.
If you want me to go to the 483s, I can go through them.
Q. Well --

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A. When you say "specifically," you mean that mention Digitek?
Q. Yes.
A. There's several.
Where Digitek's name is part of the -- is included in the 483.
Q. All right. Well, to save you time, here's what I see, and you tell me if you remember any other instances, and if you want to look at the documents, fine.
In December of -- or February of 2006, the FDA had a 483 about adverse report -- adverse incident reporting.
A. Correct.
Q. You remember that one?
A. Yes.
Q. Then in August of 2006, there was this cleaning validation test method; correct?
A. Correct.
Q. And the AER reporting was fully remediated; correct?
MR. MILLER: Object to form.
A. I don't know if it was or wasn't.
Q. That's not your area of expertise?
A. No. No, it's not.

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Q. Was the cleaning validation test method observation remediated?
A. I believe it would have been, yes. But I -- I don't recall specifically. I didn't reconcile it.
Q. Okay. And then from my review, there are three straight 483s, October of '06, November of '06 and September of '07 in which Digitek is not mentioned at all.
Do you remember that?
A. I'd have to look at them. I suspect that if you looked through it and you don't see Digitek named, that is accurate. If you want me to take a look at it, I will.
Q. In May of 2008, there were two comments about Digitek. One had to do with blend uniformity investigations and the other had to do with 70924.
Do you remember that?
A. I remember those instances, yeah.
Q. All right. If you need to look at the 483s, I want to make sure that those are the three 483s which contain any reference to Digitek specifically.
Do you need to check?
MR. MILLER: Object to form.

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MR. MORIARTY: What's the matter with the form?
MR. MILLER: It's misleading. Your whole line of questioning was -- was about mentioning Digitek specifically, and then you changed to summarizing it with -- with mentioning Digitek in any way. I forget how you mentioned it. We can certainly take a look at it again.
Q. Why don't you check the 483s and tell me if there are any other 483s, besides the three I mentioned, that refer to Digitek.
MR. MILLER: Period.
A. That use the term "Digitek" in there.
Q. Yes. As a product.
A. Okay. I understand that. But if there is -- so I can get clarify here. If they say that all so-and-so systems are -- are included, do you want me to tell you that I believe that Digitek is part of that universe?
In other words --
Q. No. I'm asking you about Digitek specifically referred to.
A. I'm trying to answer you for Digitek.
But if you say something about "all" or "every," it means that Digitek is part of the "all"

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or "every," or would be singled out as an exception.
So if I went through it, I'd have to say, okay, here are the ones that say Digitek and here are the ones that are -- that are -- are across all operations, and, therefore, Digitek is part of that, even though the name isn't there.
I'd have to literally go through -- we could go through line by line. It would be easy.
Q. I'm asking you about a product, not a system.
A. A product. Okay. So now ask the question again. Maybe I can help you better.
Q. Do you need to look at the 483s to tell me whether or not Digitek is specifically mentioned in any more than the three that I've told you about?
A. I do not need to go through it to try to find -- do a word search for the name Digitek. I will take your word that that's correct.
Q. All right. Now, you've seen references in some of these documents to a total failure of the quality system, haven't you?
A. Yes. Yes.
Q. When FDA has tested Digitek, at least seven times just in the recall batch period alone, and the product met USP specifications every time,

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you can't have a total failure of a quality system regarding Digitek and repeatedly pass USP --
A. That's absolutely not true.
It depends on what you mean by total failure.
Total failure, to me, means that you've incurred a huge risk in terms of releasing product, whether it be Digitek, whether it be the other drug products, and by -- by having this huge risk, it's a -- it's a huge problem.
Q. Well, you said in your answer it depends what you mean by total failure.
A. Yeah.
Q. What do you mean by that?
A. What do I mean by what?
What do I mean by total failure?
Q. No.
A. Total failure --
Q. No. You said, it depends what you mean by total failure.
What do you mean by that? Does that mean that total failure is in the eyes of the beholder?
A. Of course it is.
Q. Are you talking about total failure of

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the quality system from a regulatory standpoint?
A. Versus what?
Q. My question stands by itself.
A. From a regulatory standpoint, is it a total failure? If I was using the word "total failure," I would say from a regulatory and a quality control standpoint, it is a failure. "Total" is not a good word to use.
Because it -- it's difficult to quantify.
Q. But certainly --
A. It's a significant failure.
Q. Certainly product quality, as defined by the specifications, can still be met under these circumstances; right?
A. Is it conceivable? Yes.
Q. Well, isn't it a fact when FDA tested seven of the recalled batches itself?
A. It is -- if you're asking the question, can you, in a total failure mode, produce some product that is acceptable, yes, it can. Whatever "total failure mode" means.
Q. And if some -- and if -- even if we accept the FDA's statement that there was a -- somebody's statement that there's a total failure of

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the quality system, that does not tell you if there was out-of-spec Digitek in the hands of consumers, or if there was, how much there was; right?
A. That -- just that term, no. It has no -- no precision to it whatsoever.
Q. Was there ever a statement by -- I'm sorry. Let me rephrase that.
Was there ever a final agency determination, in any FDA document, that there was a total failure of Actavis's quality systems?
A. I don't know if they used that term.
I think what -- the only term that I recall definitely is when people tried to paraphrase what they felt the FDA either could call the outcome or -- that type of reference.
Q. Do you ever go on FDA's website and study their statistics about compliance actions?
A. Oh, sure.
Q. Do you know how many warning letters were issued in 2008 by the FDA?
A. No. No, I don't recall.
Q. Do you recall how many recalls there were?
A. No.
Q. Would it surprise you if there were

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2,721?
A. Recalls?
Q. In 2008?
A. Would it surprise me? It may surprise me. It's a little bit higher than I would have thought.
Q. Do you know how many 483s were issued?
A. No. It's got to be tens of thousands. It's got to be many.
Q. Do you -- do you know how often FDA issues a 483, percentage-wise --
A. It's in --
Q. -- when they do an inspection?
A. All I know is I didn't get any.
Q. I would assume that other parts of J&J got plenty of 483s; right?
A. They -- other companies did get 483s, surely, just not mine.
Q. Now, before I shift gears and get to your resume and your actual report, let me ask you an open-ended question.
If I asked you to prove to me that tablets outside the specifications for active pharmaceutical ingredient actually reached consumers, how would you go about doing that?

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A. I'd take a look at all of the -- first of all, all of the exceptions, all the out-of-specifications, all the deviations, all of the departures, whatever -- the exceptions that were done; in other words, the non-conformances that occurred, I'd take a look at those first. And then determine whether or not, based upon that, there's a reasonable probability that material would be released to the market. That would be the very first step, which was a big step; meaning energy-wise.
Q. Okay. Then what would you do?
A. Then --
Q. To check -- because at this point, you're working with the hypothesis, the reasonable -- I'm sorry. Let me withdraw that.
I would assume you'd also look at batch records and quality control testing.
A. That would not be my first step. The others I'd --
Q. I'm not asking if it's your first step. I'm asking whether it's --
A. You said approach.
Q. -- a step.
A. Is it a step? Sure.

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Q. I mean, you'd want to know whether the product passed blend uniformity, in-process testing and finished-product testing, wouldn't you?
A. Yes.
Q. Okay. What would then be the next step --
MR. MILLER: Objection to form.
A. You got me out of order. The second step would be looking at complaints.
Q. Okay.
A. And I would look at, did consumers receive product that either they had some type of medical issue, or some type of alleged issue with the conformance of the product to what their expectations were.
Q. Okay.
A. And then I'd go through those records, and I'd determine how many were confirmed and how many were not confirmed. With the confirmed, I'd say the customer got a product that was out of specification, because they sent a sample and it's out of spec.
Q. Okay.
A. Then I would -- this is off the cuff, but what I eventually -- if your question is would I

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what eventually look at the batch records, absolutely. I would take a sampling of the batch records. I wouldn't look at them all unless, for some reason, I wanted to totally quantify it.

Q. Okay. Anything else?

A. Let me think about the systems.

I would look at -- yeah. I would look at systems that affected the quality of the product. I'd take a look at process validation.

Basically I would do an audit. I would look at raw material acceptance. I would look at, as you said, batch records. I'd look at preventive maintenance. I'd look at calibration. I'd look at in the labs, at lab notebooks, to try to scrutinize.

I'd look at standard solutions. I'd see how they controlled those, and whether or not it's consistent with GMP.

I'd go into the micro lab. I'd look for -- sometimes they have a certain water quality. Normally companies do an annual report of water quality. And then I'd take a look at the water quality test results themselves.

I'd go into the micro lab. I'd take a look at the facility itself. I'd take a look at the equipment. Was it qualified? I'd ask questions

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regarding the validation -- or the qualification, rather, of those instruments, for example, an incubator. I'd ask whether or not it would have been properly qualified, the temperature distribution, whether they used qualified methods or qualified equipment to do that.

I'd go through the analytical lab. I would determine whether or not the equipment that's used to test has been properly qualified.

I'd look at the training records of those people that did the tests, to see that they were properly trained.

I would then follow through with -- on a manufacturing level -- all -- all the areas I felt that were -- could impact on the quality of the product.

Basically as thorough a job -- again, if I wanted to find out as a -- as comprehensively as human -- humanly possible, I would do that type of thing.

And I have done stuff comparable to that.

Q. You did not do all of that in this instance; right?

A. I did not, sir.

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Q. All right. Now -- but if you're reviewing the internal documents, like the exception reports, the out-of-specs, the deviations, the batch records and the system reviews, what you wind up with there essentially is a hypothesis of, maybe we did or maybe we did not send defective product out into the marketplace; correct?

A. You'd have to repeat that question.

If you do -- if you do an analysis from what standpoint?

Q. The analysis that you just gave; right?

A. Right.

Q. You --

A. I talked about the exceptions. That would have been the first thing.

Q. I understand that. But at the end of that, if you're just looking at the internal material, at the end of that --

A. Internal material.

Q. The company's material.

A. "Material" meaning chemicals, product?

Q. Everything you just described except the --

A. Those are records, documentation, etcetera.

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Q. -- complaints. Okay. Everything you described, but the complaints.

A. Yeah.

Q. You just come up with a hypothesis that out-of-spec tablets went out; correct?

A. No. I would have enough information, perhaps, to begin to find instances where product got out the door.

I mean, I would look at stability. If stability failed, product out the door was out of specification.

Q. All right. I understand that. But did you see any -- in the material you reviewed, were there stability failures for Digitek?

A. For Digitek, I don't recall seeing them.

Q. What I'm trying to find out is your scientific method to -- in your instance, you've been consulted, how do you prove that defective tablet actually got out? Okay? It seems to me that at the end of what you just described, except for the product complaints, so far you cannot actually prove that defective product left the premises?

A. No. The -- what I would say is -- now, as part of the investigation, I would look at

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retained samples. I would test retained samples. When there's -- there's enough for a duplicate assay for every single batch we produce.

I would test raw material components.

I would -- a lot of raw material components are received on certification.

I would probably do redundant testing to make sure that, again, we didn't have -- we didn't have unacceptable raw materials.

Q. What if it passed?

A. If it passed, then I would continue my investigation until I exhausted all those things that I felt could be contributory.

Q. What would constitute proof to you, just from the internal documents, that out-of-spec -- let me rephrase that question. Okay?

You've got -- let's assume you've got a very low number of out-of-spec investigations.

A. Right.

Q. Okay? Let's assume that you have no out-of-spec finished tablet testing.

A. Okay.

Q. Okay?

A. "Finished" meaning commercially-sold product --

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Q. Yes.

A. -- where you take your sample and -- and use it to release. We're not talking about stability, we're not talking about any other extra -- extraordinary testing.

Q. Well, let me -- let me continue.

A. Okay.

Q. You have a very low number of blend uniformity issues. You have no out-of-spec finished product testing. You have no stability failures.

A. The terms you're using -- I should let you complete your sentence.

Q. Because stability testing is done after release; correct?

A. Right. It's frightening. We find out months, if not years, later that what you sold is no good.

Q. Okay. But you're doing this review after the fact because you're being consulted.

A. You mean --

Q. After a company has released the product, they call you in because they want to know. Okay?

So if you've got these things, essentially, going for the product, at what point do

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you say, I think there's proof that there was defective product that's in the marketplace?

A. As soon as I find a few instances where there's -- where there was defective product.

Q. Okay.

A. And then I say, you know, do you want me to continue to go and try to quantify, try to figure out what batches, you know, it depends on the level of scrutiny that you want.

The FDA, for example, when they go in, when they see two or things wrong with a certain system, they may not continue looking at that, because they found out that the system is not adequate.

Q. All right. And if you were --

A. And that's their approach.

Q. If you were called in on a consulting job like this, for the part about the customer complaints, would you have hired one of your colleagues to come in and do the pharmacovigilance analysis of the customer complaints?

A. Wait. Pharmaco, I would, myself, want to go through, which I consider arguably the most important feed-back from the customer, which are customer complaints. I would go through. I would

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ask for a summary of all the complaints. I would ask for some explanation of what they consider critical, what they would consider trivial.

I would then ask them to sort, because they'd be in an electronic base, I'd ask them to sort what -- you know, the -- what we both perceived as being potentially critical.

I would then look at the levels, the incident levels, of those critical issues. If you have multiple batches that had the same issue, multiple products, it's 16 complaints within one batch and almost none in others. So I'd look at the trends, and then I would, myself, go through those batches that were critical, and those complaint records that are alleged to be critical, I would go through those and review those myself, because I would consider it that important.

Q. Okay. Did you personally consult directly with a pharmacovigilance expert in your work on the Digitek cases?

A. Not at all.

Q. Have you seen any reports of an expert, or from the FDA, that says that there was a pre-recall signal in the AER data to indicate that there was a problem with the drug?

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A. I'm not sure what that term is.
I guess not, because I'm not familiar with that term.
Q. Which term?
A. Pre --
Q. Pre-recall?
A. Pre-recall -- what is that?
Q. Signal?
A. Signal. I don't recall that term.
Q. To put it another way, has any pharmacovigilance expert told that there was data pre-recall to indicate that there was a problem with Digitek in the field?
A. Well, the only thing I recall was that this was -- this was one of the top, I believe number 3, most complained about product, if you will, with the most issues. So they needed a high -- they wanted a high level of scrutiny. That might have been a document from my line.
Q. Well, didn't the FDA, in that EIR that I read you from a little bit ago, say that it was the highest volume product, or one of the highest volume products?
Yes?
A. Yes. Yes.

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Q. And didn't the FDA say that it was no trend to the adverse event reports?
A. I believe that's what they said.
Q. What I'm trying to find out --
MS. CARTER: Objection to form.
Q. What I'm trying to find out from you is whether you have consulted with or seen the report of FDA, or an expert, to indicate that there was some pre-recall signal, some pre-recall evidence that there was --
A. Associated with adverse experience.
Q. -- problems -- problem with the Digitek in the field from customers.
A. From customers? I don't recall seeing that.
MR. MORIARTY: How far are we on the tape?
THE VIDEOGRAPHER: We have about another 28 minutes left.
MR. MORIARTY: All right. Let's -- we need to take a five-minute break because my colleague needs to leave. Okay?
THE WITNESS: Sure. I could use it.
THE VIDEOGRAPHER: Stand by. We are going off the record. The time is 3:54 P.M. This

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is the end of Tape No. 5.
(Recess was taken.)
THE VIDEOGRAPHER: We are back on the record. The time is 4:09 P.M. This is the beginning of Tape No. 6.
Q. When were you first contacted about being an expert in this case?
A. Oh, I'm going to guess in February, perhaps.
Q. Of what year?
A. Of this -- I'd have to -- I think it was February of this year.
Q. And who contacted you?
A. Actually, Sal Romano contacted me.
Q. Who contacted Sal?
A. John Kowalski contacted Sal.
Q. Who is John Kowalski?
A. John Kowalski is a gentlemen, he and I worked -- someone I worked with, a microbiologist, who does consulting. He took a retirement package similar to what --
Q. Who contacted Mr. Kowalski?
A. I don't know. Somebody from the law firm.
Q. I assume you're charging Plaintiffs for

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the time you spend reviewing records, writing reports, and things of that nature.
A. For the most part.
Q. What are you charging them?
A. I'm charging $430 an hour.
Q. And then today, I assume I'm being charged for the time spent questioning you; right?
A. Yes. I want to be sarcastic, but I won't be.
Q. How much are you charging me?
A. Whatever the rate would be.
Q. $430 an hour?
A. Yes.
Q. How did you come up with $430 an hour?
A. We were told that they would pay 400. We -- they asked us to bring in an expert on tableting. As part of standard consulting agreements, he would have been part of the SpyGlass. We decided that that was not the best use of Russ, but then we had a loss of income, so we said that we would like to get for ourselves another $30 an hour, which we said did seem fair enough. So each of us went from 400 to $430 an hour.
Q. When you say "each of us," are you talking about you and Sal?

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A. Sal and -- Sal, so when Sal billed -- bills -- billed, he would get $430 an hour, also.
Q. And how was it -- I'm sorry. Were you done?
A. Yes.
Q. How was it decided that you would sign the report and testify, as opposed to Sal?
A. Because Sal's schedule would not allow -- the visits, the deposition dates, the potential trials, he's beyond busy.
Q. All right.
A. So it sounded like something he could do to begin with, and he felt he couldn't do it.
Q. And then did -- the Plaintiffs sent you some material; correct?
A. The Plaintiffs sent me material --
Q. Plaintiff.
A. Yes.
Q. And you reviewed it?
A. Correct.
Q. Did you have a full opportunity to read whatever they sent you?
A. Yeah.
Q. Did you have an opportunity to ask them for additional documents if you wanted to?

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A. Yes.
Q. Did you -- did they let you know that there were depositions going on of various company witnesses?
A. No.
Q. You never knew that?
A. I suppose I knew it.
I didn't -- it wasn't important to me.
Q. All right. Did you --
A. Because it's the facts and data that I wanted to look at. I didn't -- quite honestly, never went through the deposition process, so it wasn't totally clear to me what -- what all these records -- what records would be collected, etcetera, and what would be available.
Q. So after you reviewed what they sent, did you ask to see any additional data?
A. I asked to see a ton of additional data.
Q. Did you get the data you asked for?
A. I received what they had.
MR. KAPLAN: That's not the question.
Q. Did you ask for anything that you didn't get?
A. I'm sure, yeah. I'd have to go back

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through what I requested, but, yeah.
Like I requested to go to the -- an audit, and it just -- just didn't seem -- later on, it just didn't seem practical or worthwhile.
Q. Okay. Anything else that you asked for that you didn't get?
A. I suppose there is. I'd have to go backwards -- or I'd have to go back in time and reconstruct that.
Q. Would that be documented in the E-mails, or other materials --
A. That may be documented, yeah.
Q. And then after reviewing whatever you did have available, you wrote a report.
Is that right?
A. That is correct.
Q. And your signature appears at page 35 of that report.
Is that right?
A. Correct.
Q. And you had all the opportunity to write this and include what you thought were the significant things about this litigation.
Is that right?
A. If it was available.

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Q. And you had --
A. I was told that the information is what it is at that point.
Q. And you had an opportunity later, after writing a first draft, to discuss it with the Plaintiffs' lawyers.
A. That's right.
Q. And it's come to this final version; correct?
A. Correct.
Q. And you were aware that the purpose of this was to put us on notice of all your opinions about my client, Actavis, and Mr. Kaplan's client, Mylan; right?
A. Yes.
Q. And you tried to do that?
A. I did it as well as I knew how.
Q. According to your resume, you got your bachelor's degree in mechanical engineering.
Is that right?
A. That's correct.
Q. And then you did some graduate work at Iowa State?
A. That's correct.
Q. Did you -- did you get a degree from

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Iowa State?
A. I did not.
Q. You did some graduate work in biomedical engineering at the University of Rhode Island?
A. Correct.
Q. Did you get a degree from the University of Rhode Island?
A. No, I did not.
Q. At that point, you went and started at Ethicon; correct?
A. Ethicon, Inc.
Q. Was that all devices?
A. That was devices, correct.
I worked at quality assurance supervisor, and where we did certain level of inspection, visual inspection. That was ineffective. And I worked as -- I will call it a validation engineer for the last two-plus years.
Q. Do you have any of the Six Sigma degrees or --
A. I have a lot of training, yeah.
Q. Well, do you -- do you get degrees or --
A. Yeah, I have a -- I have a green belt.

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Q. Okay. And is -- is the Six Sigma System valuable in -- in what you do?
A. Is it valuable? It's a tool. And if used properly, it can be valuable.
It sometimes is almost the opposite, but...
Because there's an expectation of what it can do that's not achievable.
Q. All right. Then you worked from '86 to '89 -- wait a minute.
A. Then I went to Corporate.
Q. Well, what did you do between '79 and '86?
A. '79 and '86, I worked in Johnson & Johnson International, which became Johnson & Johnson Corporate. I ended up going back there again. You know this HIV company I explained to you? Well, we went out of business, and as we closed the doors, I was looking for a job. There were people, apparently, even though I didn't know them, at Corporate who said, we'd be glad to have you, you know, temporarily. I had no interest in going back to the job, meaning full-time. So I worked there for almost two years until I found something that I felt was -- would use my skills.

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So I worked a total, I'll say, nine -- say nine-plus years at Johnson & Johnson Corporate.
Q. On any specific products?
A. All products. I -- I constantly moved. I can give you a little history, but it's up to you.
Q. When you were with Ortho Pharmaceutical from '86 to '89, was any of that solid oral dose?
A. Yeah. 90 percent.
Q. Did you work on any patch technology?
A. Patch -- no. It was not -- it was not a viable technology at Ortho at that particular time, that I recall.
I didn't work on it.
Q. '89 to '91, you were at IOLAB.
A. IOLAB, correct.
Q. That's another Johnson & Johnson company?
A. Yes.
Q. Was it solid oral dose?
A. No. It was interocular devices, implantable devices, and also phacoemulsifier, emulsifiers, which are electronic instruments used during surgery, and we did -- they did chemicals, but I don't think they're -- I don't think they're -- no. They're a device, not a drug.

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Q. '92 to '95 at Advanced Care Products, was that solid or oral dose?
A. No. That was topical.
Q. '95 to '97, Direct Access Diagnostics.
Was that solid oral dose?
A. No, it was not.
Q. Johnson & Johnson CPWW from '98 to '04.
Was that solid oral dose?
A. There was -- there was one, but there were two to three, different -- most of it was topical, and we did have some solid dosage form products.
Q. When you worked on solid oral dose products at Johnson & Johnson, did you ever have batches that were put on hold?
A. Did we -- of course.
Q. Did you -- I assume you rejected batches from time to time?
A. Rejected batches from time to time, yes.
Q. I didn't ask you this when I was asking you about what you charge for litigation consulting, but do you know what you charged the Plaintiffs' lawyers to date for this litigation?
A. Well, I have one bill in. I don't

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remember exactly, but we just got paid. Probably -- I don't remember. 20-some-odd-thousand would be for me.
Q. Billed?
A. Billed. Yeah. I would get about $25,000.
Q. And how much unbilled time do you have?
A. I don't know. But it's probably equivalent to that.
Q. So you may have as much as $40,000 worth of work into this case even before today?
A. Yeah, I would say yeah.
Q. 40 or 50.
A. Yeah, I put in a lot more hours that I'm not billing, but when you put in a 16-hour day, I bill for 8.
Q. Have you talked -- other than with somebody from Motley Rice, or Pete Miller, and Sal, have you talked to anybody else about this litigation?
A. Not a human being, other than they know I'm doing some kind of litigation. That's it.
Q. Do you advertise yourself as an expert in any trade journals of any type?
A. No. No. I do not.

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Q. Have you seen the expert reports of any of the other Plaintiffs' experts in this case?
A. No. Not a single one.
Q. Do you have any military experience?
A. ROTC.
Q. Where?
A. University of Dayton. It was required first two years.
Q. Where are you from originally?
A. New Jersey. Jersey City I was born in.
Q. Have you ever had a faculty position at any school?
A. No.
Q. Have you ever published any articles about quality work in the pharmaceutical industry?
A. I -- I have published, if you will, within Johnson & Johnson Worldwide. I was the creator of Johnson & Johnson Worldwide guidance documents when I was there, and I wrote procedure -- not procedures guidance documents, that affected all companies worldwide. So they would read it and they would use that as a minimum acceptable approach to -- to -- that quality control subject.
Q. Have you ever published anything outside Johnson & Johnson?

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A. No. I had no interest in doing it.
Q. Have you ever taught at any seminars on quality assurance outside --
A. Seminars, no. I trained --
Q. -- outside J&J?
A. Outside J&J, no.
Q. So do you consider yourself to be an expert in regulatory for the pharmaceutical industry?
A. I consider myself an expert on systems and controls.
Q. Quality systems?
A. Quality systems and controls.
MR. KAPLAN: Was that "no" to regulatory?
THE WITNESS: Well, it encompasses regulatory. It's interpretation of regulatory and in real fashion.
My -- my objective -- my objective -- well, I can explain it. My objective --
MR. KAPLAN: Well, he's asking the question. I just didn't hear. I didn't know whether you -- he asked the question, do you consider yourself an expert in regulatory affairs.
THE WITNESS: In regulatory affairs --

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MR. KAPLAN: And I didn't hear that.
A. Regulatory affairs is a much bigger picture. I do not consider myself expert on regulatory affairs. Regulatory affairs would -- would go into reporting. It would go into other aspects, medical aspects, which I have no -- no experience in, and no interest.
Q. In Tab 3 of the documents that were contained in your Appendix B is a 483 from 2004. Do you remember that?
A. Well, I've read them all, so, yes, I would remember it.
Q. This precedes the recall of Digitek; right?
A. 2004, yes.
Q. And --
A. Do you want me to pull the document? Is that worthwhile?
Q. Digitek isn't mentioned in this 483, is it?
A. I don't know. I'd have to look at it.
Q. I'm handing you my copy of that 483.
A. The name "Digitek" does not appear on that document.
Q. And since this precedes by -- the

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recall by several years, and since it doesn't refer to Digitek, can we agree that this 2004 483 has nothing to do directly with whether any consumer got out-of-specification Digitek?
A. No. I would not say that.
Q. Why not?
A. I would say any time there is GMP concern that affects -- potentially affects across a system, I'm always concerned, as a quality professional, that we could have released -- if it's my company -- that we could have released defective product.
Certainly, we are releasing, if it's significant enough, adulterated product. Now let's determine whether or not a defective product, as we would define as out-of-specification, went out the door.
I would take that 483 very seriously.
Q. Well, I'm not suggesting you wouldn't, and I'm sure -- would you agree the FDA takes these seriously?
A. I think that's their job, so I would make that assumption.
Q. So if they had a concern about Digitek, and found either GMP violations or

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out-of-specification results for Digitek, it's likely that they'd address it in this 483.
A. I don't know. You'd have to talk with them.
Q. Tab 4 in your Appendix B was a Complaint For Permanent Injunction.
Are you an expert at all on the legal effect of a Complaint For Permanent Injunction?
A. No, I am not.
Q. Have you ever been sued?
A. No. Thank goodness.
Q. Have you ever sued anyone else?
A. Never will.
Q. Well, you might have a customer stiff you. You might want to sue them for your fees.
A. I would never do that.
Q. You get it all up front?
A. No. The exact opposite. If I don't understand that customer well enough that I know I'm going to get paid, it's my fault.
Q. Okay. But you --
A. So I would not sue them. No.
Q. You don't know what the legal import of this document is.
A. No, I don't.

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Q. Do you know what a complaint is, just an accusation?
A. I believe I do.
Q. Not -- not proof of what's contained it?
A. Right.
MR. MILLER: Object to the form.
A. I believe that's correct, but I'm not an expert on the subject.
Q. In Tab -- I already asked you that. Your Reference 14 was Plaintiffs' Exhibit 137. Okay?
And it's -- I'm not sure who drafted it, but it's essentially a summary of an August 2006 GMP inspection.
Is that right?
A. Yes. It appears that.
Q. Is there anything in that document about out-of-specification Digitek?
A. I'd have to look through it.
Q. Go ahead.
MR. MILLER: I object to form in that it's misleading. Sometimes you say "specifically Digitek," and sometimes "Digitek." So you need to let him know --

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MR. MORIARTY: What's the difference?
Q. Is the word "Digitek" in that document? Did it talk about Digitek out-of-specs?
A. Repeat your question. I don't have to look at -- I see you have it.
Q. What's the difference between "Digitek" and "specifically Digitek"?
A. Can I give you an example?
Q. Because I'm going to get a mouthful about, well, if they say it about Aprodine, it must apply to Digitek.
I want to know if Digitek out-of-spec is in that document. That's what I want to know.
A. In -- indirectly.
Q. Directly. Is Digitek --
A. No, not Digitek --
Q. -- out-of-spec in there?
A. I'm not trying to wordsmith it, but the word "Digitek" does not appear in this document, that I could see.
Q. Okay. Well, when you say indirectly, show me what you're referring to.
Give me an example.
A. We'll take the first one.
"Failure to fully investigate errors.

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All lab data not included with batch records. Manufacturing deviations not always documented."

Well, that's a situation where you don't know whether it includes Digitek or not, and the assumption has to be, since there are so many examples, that the system is out of whack, and that you would have no way of assurance that if Digitek had an issue, it would be part of the examples that they looked at.

Q. Have you done anything to determine whether, in fact, Digitek was ever determined to fall into this broad heading?

A. The -- I don't need to do that.

Q. Why not?

A. Because when a quality system that cuts through a company is found to be out of control, it implicates all of the products. And certainly when I looked through records, I would look specifically for the name Digitek, and if I found it, I would try to make note of it and try to understand if it was one of the specific examples that were used.

If you say that the -- if you don't have a system to report out-of-specifications, I'm never going to see the -- unless I looked at the hard data, you know, going through laboratory

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records that don't appear in batch records, there would be no way of me knowing that they occurred unless I looked at them.

So by saying that I can't find them, I'm saying that, you know, that Digitek is part of that. I can't find if it did exist.

MR. KAPLAN: I'm going to move to strike the last answer as not responsive to the question that was asked. You were asked, did you do anything to determine. Your answer was, I don't need to do it. The question was, did you do anything. Yes or no. Did you?

MR. MILLER: And that is an answer, yes and no is not always required.

MR. KAPLAN: Did you do anything?

THE WITNESS: Did I do anything? Yes. Did I --

MR. KAPLAN: Did you follow up on that?

THE WITNESS: I -- I followed up on --

MR. MILLER: Objection. Asked and answered.

THE WITNESS: -- in that -- in that. I had a limited amount of information that was given to me.

When I see, let's say, a qualified

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individual come up with example after example, and find that there is significant holes in the system, particularly where the information -- they're saying the information is not processed, it's not even -- they don't even discover it. Then I have to make the inference that it includes the entire population of products, of which Digitek is part of that population.

You don't know what you don't know.

MR. KAPLAN: So everything you're saying is based on an inference.

THE WITNESS: It is not an inference.

MR. MILLER: Objection to form.

MR. KAPLAN: That's what you said.

THE WITNESS: No, I did not say -- well, if I said "inference," I used the wrong word. I would say it's part of -- it would be -- do you want me to explain?

MR. KAPLAN: I really don't.

THE WITNESS: Okay.

MR. KAPLAN: I really want you to answer that question. That's why I moved to strike.

MR. MORIARTY: Let me get back on my track.

Q. This is a -- the first column of this

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Plaintiffs' Exhibit 137 is a statement out of a 483 observation or a warning letter; correct?

A. I believe that's correct.

Q. Which we established six hours ago, or more, was not a final agency action of the FDA; correct?

A. Correct.

Q. So would you concede that this may not apply to Digitek, this observation?

A. Okay. It -- it -- could I concede that there are -- there's a possibility that, for whatever reason, a system breakdown only occurred with the specific examples that they found? I would say there's a possibility, not a high probability.

Q. Okay. But you are assuming this applies to Digitek. Is that right?

MR. MILLER: Objection to form.

A. I'm assuming that it applies to everything, because it is a system issue. It's like you -- if you go to five places, only five places, and you find people weren't trained, you make the assumption. You're not going to go to every single -- do a 100 percent inspection, if you will, of every single position to find out if they're adequately trained.

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You have enough information to say the training program is not in effect.
Q. Okay. So you're assuming it applies to Digitek, is the short answer.
MR. MILLER: Object to form.
A. You say -- you say I'm assuming.
I'm saying that the system -- there's a system issue. Digitek is affected by that system; therefore, it does not have a reliable system and, therefore, affects, or potentially affects, Digitek.
Q. But you haven't seen any direct proof of this problem with Digitek, from this Exhibit 137.
A. No. I have not seen the name Digitek associated as -- as an example with that.
Q. All right. And in just for this example, "The failure to fully investigate errors, all lab data not included within batch records," does not necessarily indicate that the final product was outside its specifications, does it?
A. Quality -- I'll tell you how the a quality assurance and myself --
Q. Yes or no.
A. You have to repeat it.
Q. No. I want to know -- I want to know whether this specific observation, "Failure of the

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quality unit to fulfill its responsibilities," is the general statement. "Failure to fully investigate errors, all lab data not included within batch records," that doesn't necessarily mean the finished product is going to be out of specifications, does it?
MR. MILLER: Objection. Asked and answered.
Q. Even for the specific product they're talking about here.
Is that right?
A. Can I reread it again, please?
Q. Sure.
A. I have no specific examples that I know of where the FDA has found that would fall under this category, specifically to Digitek. This -- it falls under this category because it's part of a control system that affects the quality of Digitek product.
Q. And my next question, which I would like an answer to, is whether the failure to fully investigate errors and all lab data not included with batch records, that doesn't necessarily mean that the finished product is out of specification. Is that correct?

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A. It sure -- it sure potentially implicates it as a potential out-of-specification.
Q. Potentially.
A. Correct.
Q. But it doesn't necessarily --
A. No.
Q. -- follow as night does day.
A. Correct. That is correct.
Q. Your Tab or Reference 15 is Exhibit 25. A February 1, 2007 warning letter. Okay?
Does it say anything in there about Digitek tablets being out of specification, or equipment used to make Digitek being not qualified?
A. I'm going to have to read it.
Q. Fire away. Specifically.
A. I understand -- I understand your question now.
If I can breeze through this, there are no products specifically mentioned in this.
Q. Okay.
A. At least as I'm going through it.
Q. All right.
A. They talk about system failures.
Q. Your Reference 21 is Exhibit M-16 from

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Susie Wolf's deposition.
Do you see that?
A. Yes.
Q. And it's a document about Batch 80202 A; correct?
A. Yes.
Q. And a hold was put on that batch.
Is that right?
A. That is correct.
Q. Now, do you know whether that batch was ever distributed to the market?
A. 802 -- 80202 A, bulk tablet was released --
THE REPORTER: Sir, you have speak up, and speak slowly.
THE WITNESS: Oh, I'm sorry.
Q. Talking to yourself is a bad idea.
A. I was talking to everybody. You just didn't hear me.
The -- what I put down here, and I believe it's accurate, is, "Bulk tablet lot was released to fill and packaging, only later to be placed on hold due to a tablet weight issue. They indicated that this is one of the problem child."
This is grammatically incorrect, but --

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so what -- what this implies is that they found out in packaging that which they should have found out in tableting. Okay? In other words, a product that is out of weight should not -- or any defect, for that matter -- should not be discovered in a subsequent operation.

Q. But it was discovered and not released to the market; correct?

A. It appears that way, yes.

Q. You won't find it on the recall list; correct?

A. I'd have to compare it to the recall list, but I would make that assumption.

Shall I give this back to you?

Q. In your references was number 26, which is Exhibit M-14 from the Wolf deposition.

A. Yeah.

Q. It's an E-mail, and it says here, "Connie," and it gives two batch numbers, "have assays too low." Do you see that?

A. Yes.

Q. And then it gives numbers of 96.2 and 97.3 as the assay numbers; correct?

A. Um-hum.

Q. Are you familiar enough with the USP

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monograph to know that those assays are well within the specification?

MR. MILLER: Object to form.

A. The way I read this, they could put 100 percent. It is not what I'm looking at.

When somebody says, in management, Susie Wolf says that the assays are too low, these may or may not be accurate information. Something is going on. You just don't say something is within specification when, in fact, it's not. Only a person who should be working for the competition should be saying that.

And they are looking now at another batch, 71004 A1, because, apparently, it's not being implicated with a low assay. So that number, to me, is immaterial. This is -- this is not somebody who's saying the specification is, the USP states X, this is -- this is -- and, therefore, this is Y, and, therefore, it's out of specification, or it's in specification.

Q. Do you know who came up with those assay numbers?

A. No.

Q. So you don't know whether those are from Actavis or not; right?

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A. Whether they're -- no. I don't know where those numbers came from.

Q. Do you know whether Mylan or UDL subsequently had Celsis labs test any of those batches?

A. No, I don't.

Q. Do you know, in fact, whether or not those particular batches were out of specification, by anybody's measurements?

A. Give me the batch numbers again, please.

Q. 709 --

A. I'd like to look at them myself.

Q. Sure.

A. Okay. Please ask your question.

Q. Okay. My question was, do you know whether or not these batches were ever tested as actually out of spec by anyone?

A. No, I don't know if they were.

Q. In fact, do you know whether -- withdraw that last question fragment.

Okay. In your references was number 33. It was a Plaintiffs' Exhibit 172. It's an E-mail at Actavis from Jisheng Zhu, J-I-S-H-E-N-G, Z-H-U, in March of 2008.

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Do you see that?

A. Yes.

Q. And he's referring to three impurities in some Digoxin batch test.

Do you see that?

A. Yes, I do.

Q. Do you know whether, in fact, these were investigated?

A. Were they investigated? I don't know. I'd have to go back and research it.

No, I don't know if they were investigated.

Can I read the statement again?

Q. Sure.

A. This appears to be self-explanatory. Someone that said that they took a look at the results, released data, and then all three lots showed high impurities. It's quite simple.

Q. No. My question is: Do you know whether these instances were investigated?

A. No, I do not know if they were.

Q. Do you know anything about whether the impurities, if there were impurities, affected the potency of any of these three lots?

A. I am not technically qualified to

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answer that.
Q. Your Reference 45 is a 483 and some associated data from 1999.
What was the specific relevance of a 1999 483 to your opinions in this case?
A. 45? I was looking for the -- any repeat pattern.
Q. Okay. A repeat pattern of regulatory issues?
A. Of GMP issues.
Q. And there is nothing in this 483, your reference number 45 --
A. Yes.
Q. -- about Digitek, is there?
A. Can I read it one more time?
Well, the products are crossed out. I would have no way of knowing.
Q. Well, just so you know, we didn't redact Digitek out of it, because that's what the litigation is about.
A. Okay. So my assumption is that none of these are Digitek, that Digitek name does not appear in this document.
Q. Okay. May I have that back, please.
Number 52, reference 52, is Plaintiff's

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Exhibit 168. It's a packaging memo about why there were two additional Digitek bottles in the repackaging of 70924. Okay?
What was the significance of this to your opinions in this case?
A. Okay.
Q. If any.
A. I did have some.
The -- this memo, or whatever it is, is issued by Scott Talbot. It is undated. It is unapproved.
What that immediately tells me, forget about the content, per se, he is trying to explain why something happened.
An unapproved, undated document is -- is not a -- does not provide me evidence that an adequate investigation was done. Here I see what looks like some logical accounts of what the person did, and trying to explain why -- why they had extra tablets as a result of something that should have had less tablets.
So I'd say -- I looked at this immediately from a GMP compliance standpoint. How could you possibly issue a memo that's not dated, not signed, and should be part of an investigation.

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It's horrendous.
Q. Well, it doesn't say there are extra tablets, does it? It says there are extra bottles.
A. Extra bottles, which means extra tablets.
Q. Well, if the fill machine is off by a tablet even every couple bottles, it is going to fill additional bottles; correct?
A. If it is off by a fraction -- I'm sorry. Could you repeat that?
Q. The fill machine is putting maybe 100 tablets in a bottle. I think for this batch, I think they were all 100. I don't remember what the bottle count was.
A. Yeah.
Q. But even if it is off by one tablet every couple of bottles you are going to get extra bottles, aren't you?
A. Using your assumption, if there is -- if the original process put more tablets in than the labeled amount, and then the subsequent process put the correct amount in, then one would assume that the reasons for extra units is due to the fact that you put too much in to begin with.
Q. And that can happen; right?

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A. That can certainly happen.
Q. Okay. Because these filling machines are not accurate enough to regularly put in 100 tablets per bottle, through a run as large as this; correct?
A. Correct. I would like to offer my experience, though.
I have found very, very few instances where a company put too many tablets in. In fact, I have seen quite the opposite, and I can provide examples, if you like.
Q. Well, that's not the issue with this.
I think the point you were making is --
A. GMP.
Q. -- to you this is a GMP issue about is this signed, authorized, etcetera.
A. Because the value, even if it were a very logical explanation, the value of it is nil. It is a gross violation of GMP. And how that document could have been created and distributed, and how anybody would have received it and not kicked it back to the original person to make sure it wasn't signed or dated, is beyond me.
It's a total -- talk about a breakdown, this is a significant breakdown.

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Q. Okay. And that is a classic example of how a -- in your view, a GMP violation may not affect the identity, purity, or potency of the tablets in the bottle; right?
A. No. No. I don't agree with that at all.
I know nothing about that. They had an overage. Everybody would have expected that they lost tablets. In other words, when they are doing their inspections, they are going to see tablets, perhaps, that have specks on them, that have chips on them. Every time you handle a tablet you will abuse the tablet and ultimately end up with, perhaps, cosmetic issues, but -- content issues, too, if it has a chip.
So one would logically assume as part of the ongoing production and handling of that, that that number would dwindle.
There are no records in the 100 percent inspection that even -- even referred to were there any other defects found. All it refers to is that there were 20 total from that particular batch.
So it is void of information. And I make no assumptions on a letter that's not signed. I -- I would say that that is a classic GMP issue,

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of which I wouldn't respond to the content because it is unofficial.
Q. Okay. I am not asking about the content of the memo.
You wouldn't use your reference 52 as a GMP violation that proves that the tablets were out of specification, would you?
A. Let me see how I used it, please.
I'm having a hard time finding those small -- 53. Here's an example -- ask your question. I'm sorry.
Q. I want to stick with your reference 52.
You wouldn't use this memo as proof that the tablets in these bottles were outside the USP specifications, would you?
A. I would use that -- I -- I couldn't use that as an example. What it tells me, though, is things are so lax associated with that particular process, I now question the competency of the people that are even writing and reading these things.
So if I -- if I don't feel confident in the person, now I really have an issue. It is a bigger issue than the content in that explanation.
Q. Your reference 60 is to the "all product recall" that followed the Digitek recall.

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Is that correct?
It's a press release.
Here you can look at it. Right here.
A. Yes. Yes.
Q. Are you aware --
A. I cut and pasted that.
Q. Are you aware that that recall was not to the consumer level?
A. I believe that I was aware of that, yes.
Yes, I was aware.
MR. MORIARTY: All right. The next thing I want to get into is his report.
Off the record, please.
THE VIDEOGRAPHER: Stand by. We are going off the record. The time is 5:01.
(Exhibit 47, Expert Opinion of Mr. Kenny and CV is received and marked for identification.)
THE VIDEOGRAPHER: We are back on the record. The time is 5:14 P.M.
Q. Mr. Kenny, I had marked as Exhibit 47 a 50-page document.
Do you see this?
A. Yes.

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Q. And the beginning of it is your report in this case.
Is that right?
A. Correct.
Q. Also contained within Exhibit 47 is -- are a number of appendices.
Is that right?
A. Well, at the tail end.
I think it started with my resume.
Q. Right. Here is the list of appendices at page 36.
Is that correct?
A. Yes.
Q. And then the appendices are your CV.
A. Right.
Q. B is the references. C is a chronology of lot 70924.
Is that right?
A. Yes.
Q. D is a press release of the Digitek recall.
Is that correct?
A. Yes.
Q. And E is what I call the all products recall press release.

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Is that right?
A. Yes.
Q. And then F is a summary of FDA observations and events.
A. That's right.
Q. Do you know who drafted the summary?
A. I did.
Q. Summary of FDA observations and events?
A. Yes. I went through the observations and tried to put them into layman's terms, hopefully, or more easily understood terms.
Q. Okay. Now, we issued a notice for your deposition.
Did you actually see the notice?
A. Yes, I did.
Q. And it asked you to bring a certain group of documents, did it not?
A. Yes.
Q. Let me go through some of the ones that I have questions about.
Number 2, "All correspondence, communication between the witness or anyone acting on the witness' behalf, and attorneys representing Plaintiffs in this Digitek litigation."
Did you bring all the correspondence?

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A. No. I -- I didn't have the time to do it.
Q. You are going to supply it?
A. Absolutely. I'm obligated. I personally feel obligated.
Q. Has -- is Sal signatory to any of the correspondence with the Plaintiffs' lawyers?
A. What do you mean by "signatory"?
Q. Signed.
A. No. His name -- his signature is nowhere.
Q. Has Sal billed for time related to the Digitek litigation?
A. Yes, he has.
Q. Does he bill you or the Plaintiffs' lawyers?
A. He, in essence, bills me, and then I put it into the -- I put it into an invoice which goes to the Plaintiffs' lawyers.
Q. Are you doing any other litigation consulting besides the Digitek litigation?
A. I have never done it, and I'm not doing it.
Q. Okay. This is the only one?
A. This is it.

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Q. When you consult with pharmaceutical clients, do you bill them by the hour?
A. I try not to bill by the hour, per se.
What I try to do is no greater than, because I know what it's like to receive a bill. So what I do is I try to very carefully craft what my deliverables are. I craft exactly how I think I am going to get to that deliverable, how much time it is going to take.
I try to put some allowance in there for invariably stuff happens, but I put very little of that in. And then I tell them that I am going to bill by the hour but it will not exceed that number. And that's the way I have done 90 percent of my billing. This is an exception.
Q. And what do you bill pharmaceutical clients per hour?
A. Well, it depends upon -- I am going on an audit to Wales. I am going to bill them 300 and -- about $300 an hour.
Q. Do you bill any of your pharmaceutical clients $430 an hour?
A. You mean like -- no. No is the answer.
Q. Item 3 on what we asked you to bring is, "All other documents prepared by the attorneys

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for the Plaintiffs and sent to you."
Did you bring those?
A. No, I did not bring them with me.
Q. You are going to produce those?
A. Yes. I am going to produce exactly what you asked for.
Q. Do you have a retainer agreement with them?
A. I received a retainer.
Q. Do you have a retainer agreement?
A. I don't even know what that is.
Q. A fee agreement.
A. A fee agreement? Oh, yes. Yes.
Q. Is that among the correspondence that you will produce?
A. I wasn't realizing that was part of it, but I will be glad to produce that.
So it also includes any business dealings. Is that it?
Q. It does.
A. Okay.
Q. It says here -- number 6, all bills that you've rendered to the attorneys and law firms in connection with this.
A. Yes, I do. Since I knew I couldn't do

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it, I didn't go through it with a fine-tooth comb to determine how to get it.
Q. And --
A. Which I will, though. I will go through that with a fine-tooth comb.
Q. And I think you said you issued one bill?
A. That's right.
Q. For what period of time did that cover?
A. That covered up until, I don't know, March -- March sometime.
Q. When is the next bill going to go out?
A. The next bill is going to go out almost immediately. But I was waiting to get the money before I sent a second bill.
I don't want to say money is not an issue, but it's not -- it's not my driving force.
Q. I understand.
Number 9, everything that you reviewed that indicates that Plaintiffs ingested defective Digitek.
What did you bring responsive to number 9?
A. Would you repeat that again?
Q. It says --

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A. I haven't read it in that detail.
Q. It says, "Everything the witness reviewed that indicates that the Plaintiffs ingested defective Digitek."
A. What did I bring to where? As part of the --
Q. Well --
A. -- reference information and stuff that I read?
Q. You were supposed to bring any documents that indicated that Plaintiffs, people, consumers --
A. Yeah.
Q. -- who have sued my client, actually took defective Digitek.
A. I haven't even thought about that question. I would have to think about it, determine what -- what I've sent to them and then, basically, formulate whether or not it falls into that category.
Q. Did you read any medical literature?
A. No, I have no interest in it.
Q. Now, you mentioned Mr. Kowalski, or someone else --
A. John Kowalski.

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Q. John Kowalski. Has he billed any time to the Digitek work?
A. I have no idea. I haven't talked to John in years.
We know each other through a lot of dealings years back.
Q. And to whom do you send your Digitek bills when you send them?
A. I send them through Meghan, which goes to some -- I don't know, somehow they pay it.
Q. Okay.
MR. KAPLAN: So you haven't been paid?
THE WITNESS: No. We did get paid two days -- we received a check either Monday or Friday. I don't recall.
MR. KAPLAN: You just said you hadn't been paid.
THE WITNESS: No. No. No. I said I got -- I did receive a check. And I said now --
MR. KAPLAN: How much was it?
MR. MILLER: Objection. Asked and answered.
THE WITNESS: To be honest, I am not trying to avoid it, the money is not that much of an issue to me. I just kind of throw more money in the

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bank. It's not why I do this job. I don't do it so that I can count up all this money. I do it because I enjoy it, and I'm helpful, and I get paid well in all of my assignments.
Q. Does Sal have an ongoing role, or do you contemplate one in the Digitek consultation?
A. No. I have no intentions of involving him at all. It would be inappropriate at this point.
Q. In 2010, to date, how much of the income of SpyGlass is related to the Digitek litigation work versus your pharmaceutical consulting?
A. Well, I have contracts for -- I figure 100,000, I have another contract for 40,000, so that's 140, I'll get -- I am going on a proposal tomorrow and I'm going to get it, and that will be billed at somewhere between 250 and $300 an hour, depending on the work, because it is not as technically challenging, so I like to keep it lower if it is not using my -- my -- my strategic abilities.
So having said that, right now, based upon what I know I'm going to get, it -- the 25, whatever it is, thousand dollars represents one -- I

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don't know, one quarter, or something like that.
MR. KAPLAN: I'm -- I'm going to move to strike that last answer.
The question was simply to date, not what you're going to get, not what --
THE WITNESS: But I have contracts.
MR. KAPLAN: It was, to date, what percentage of your income has been represented by your consulting. It is to date.
MR. MILLER: He is attempting to answer that.
A. Well, I got 22, I got -- to date probably half of that one. So to date 75,000, so this is one quarter. If I am getting 100,000, this is one quarter.
Q. Okay. And what percentage of your time is the Digitek litigation versus your consulting work?
A. The time? Over the last several months, it's been very high. Higher than I anticipated. And it represents probably half.
Q. Okay. And how many times before you wrote your report did you have in-person meetings with the Plaintiffs' lawyers?
A. Before I wrote the report? I had no

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in-person meetings.
Q. All the communication was --
A. Was on the phone.
Q. -- phone or E-mail?
A. Yes.
Q. Did you have any video conferences with them before you wrote your report?
A. No.
Q. Did you meet with them in person regarding the revisions to your draft reports?
A. I met with them once regarding the revisions.
Q. When was that?
A. Oh, a month ago, something like that.
Q. And with whom did you meet before today to prepare for your deposition?
A. To prepare for my deposition, I met with nobody.
Oh, you mean met with physically?
Q. Yeah.
A. Before -- well, before today, I met last night.
Q. With whom?
A. With Meghan.
Q. For how long?

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A. You mean how long did we talk about work, or how long did I see her?
Q. How long did you spend preparing for your deposition?
A. You mean with her or without her?
I have to understand what you are talking about.
Q. With Meghan.
A. Oh, with Meghan? I don't know. An hour.
Q. Obviously, you spent time reviewing documents again.
A. Again, I went back and reread, you know -- reread this, took a look at some of the 43s, tried to -- yeah. Took a look at those kinds of things.
Spent very little time with Meghan.
We did go to dinner together, but that was all casual.
Q. And, at the outset of this project, what was your understanding of what your function was or your role?
A. My role was to determine whether or not this company was in compliance with GMPs over a certain period of time, which turned out to be 2004

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to 2009, and to determine whether or not products that were violative were released.
Q. I understood your answer except for one word.
When you said "violative," do you mean violative of cGMP regs?
A. cGMP regs, yes, and whether or not defective product was released.
Q. When you say "defective," what do you mean BY defective?
A. Product which does not meet finished product specification requirements or stability requirements.
Q. I'm sorry. Defective, in your mind, means doesn't meets stability requirements or what was the other element?
A. Does not meet product specification requirements.
MR. KAPLAN: You said "finished products."
A. Finished. Products specif --I understand that you -- I am going to correct myself and say product specifications.
Q. Okay. And what product specifications?
A. Any specifications that would implicate

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that a defective product was in the field.
So it could be, let's say, content uniformity, or bulk specification testing, tableting, packaging, finished product sampling, stability testing, any point along the way which would also implicate or -- or you would determine that defective product either was or highlight that it could have been released.
Q. Okay. So is it your opinion that product that didn't meet stability requirements for Digitek was released to consumers?
A. You are going to have to repeat that question.
Q. Do you have an opinion, to a probability, about whether Digitek that didn't meet the stability requirements reached consumers in the recalled batches between 2006 and 2008?
A. Stability, I have no -- I saw no data to suggest that that would have been an issue.
Q. Do you have an opinion, to a probability, that product that did not meet the USP finished product specifications made it to consumers between 2006 and 2008?
A. I think product did reach the consumer s that is out of specification to a reasonable

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degree of certainty.
Q. Now, I asked you earlier how much product, how far out of spec, all of those things, and you had no opinions to quantify it; correct?
A. Correct.
Q. All right. So what is the basis for your opinion that product not meeting the USP finished product specifications made it to consumers?
A. Because of there are so many systemic system issues, that it's -- it's difficult for me to believe that product didn't get through. And in my heart of hearts that's what I believe.
Q. So if I had to summarize the methodology of your analysis for that answer that you just gave me, you look at the cGMP violations, and you conclude or opine that it is, therefore, difficult for you to believe that out-of-specification product didn't get through?
MR. MILLER: Object to form.
Q. You can answer.
A. You are going to have to repeat it, please.
MR. MORIARTY: Read it back, Carol, please.

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(Requested portion is read.)
A. I would say that's accurate.
MR. MILLER: It is after 5:30, Matt. Is this is a good time to wrap it up?
MR. MORIARTY: This is probably the perfect breaking point.
MR. KAPLAN: Before we go off the record, and I know that Matt has not finished his questioning -- I'm Harvey Kaplan, and I represent Mylan.
THE WITNESS: I'm sorry. What?
MR. KAPLAN: I represent Mylan, the other Defendant --
THE WITNESS: Yes.
MR. KAPLAN: -- in the litigation.
So I haven't had a chance to examine you. I will have a chance when you come back.
There was a notice sent for your deposition here today, and you said you saw the notice.
THE WITNESS: Yes, I did.
MR. KAPLAN: And it -- it lists 13 categories of documents that you were requested to bring.
THE WITNESS: I'll assume that's

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correct.
MR. KAPLAN: And I want you to please, before your next deposition, not only carefully review those 13 categories, but please bring those documents with you, because we will surely ask you for all of those things. Okay?
THE WITNESS: Understood.
MR. MILLER: And just to be clear, Harvey, when you said Matt was finished asking questions --
MR. KAPLAN: I said he was not finished.
MR. MILLER: Not finished. Okay. I'm sorry, Harvey.
MR. KAPLAN: I said Matt has not finished. I've never gotten to begin my questioning.
MR. MORIARTY: I have not finished.
MR. MILLER: I totally understand. And I will have questioning, as well, so...
MR. KAPLAN: Good. Then we shall meet again another day soon, I presume. Probably the same place.
THE WITNESS: This place is fine with me.
MR. KAPLAN: If that's okay.

MR. MORIARTY: All right. Off the record.

THE VIDEOGRAPHER: Stand by. We are going off the record. The time is 5:35 P.M. This is the end of tape number 6.

(Proceedings concluded at 5:34 p.m.)

J U R A T

I DO HEREBY CERTIFY that I have read the foregoing transcript of my deposition testimony and I certify that is it true and correct to the best of my knowledge.

Mark G. Kenny

SWORN AND SUBSCRIBED
BEFORE ME ON THIS
DAY OF 2010

Notary Public of the State of

ATTACH TO DEPOSITION OF: Mark G. Kenny
IN THE MATTER OF: In Re: Digitek Product Liability Litigation

DATE TAKEN: June 29, 2010

E R R A T A S H E E T

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CERTIFICATE

I, CAROL ANN SHEPARD, a Certified Court Reporter of the State of New Jersey, License No. 30X100101900, do hereby certify that prior to the commencement of the examination, MARK G. KENNY was duly sworn by me to testify the truth, the whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place and on the date hereinbefore set forth.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

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Certified Court Reporter of the State of New Jersey

Dated: July 2, 2010